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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, 2022

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.)
295 Madison Avenue, Suite 2400 NEW YORK, NY	**10017**
(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, 2022 (based on the closing price of $1.95 on June 30, 2022, the last trading day of the registrant's most recently completed second fiscal quarter), was approximately $53,095,760. 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 37,991,746 as of March 28, 2023.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's proxy statement for its 2023 Annual Meeting of Stockholders currently scheduled to be held on June 12, 2023 are incorporated by reference into Part III hereof.

Eyenovia, Inc.
Form 10-K
For Year Ended December 31, 2022

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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 estimates regarding expenses, future revenue, capital requirements and our need for additional financing and other financial items; any statements of the plans, strategies and objectives of management for future operations; any statements about the advantages of our product candidates and platform technology; estimates regarding the potential market opportunity for our product candidates and platform technology; statements regarding our clinical trials; 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 and hire necessary employees and appropriately staff our operations; 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 might not be able to continue as a going concern, which would likely cause our stockholders to lose most or all of their investment.
- Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and its financial condition and results of operations.
- We will need to raise additional capital in order to continue developing our product candidates and to manufacture and commercialize them.
- 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.
- Our relatively short operating history may make it difficult for investors to evaluate the success of our business to date and to assess our future viability.

Risks Related to Development and Commercialization of Our Product Candidates

- We are dependent on the success of our Mydcombi, MicroPine, and MicroLine product candidates and our and our licensees ability to develop, obtain marketing approval for and successfully commercialize these product candidates.
- Delays in the commencement or completion of clinical testing of product candidates we are developing or may develop in the future may occur and could result in significantly increased costs and longer timelines and could impact our ability to ever become profitable.
- Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval and limit the commercial profile of an approved label, and such side effects or other properties could result in significant negative consequences following any marketing approval of any of our product candidates.
- We might not be able to develop marketable products utilizing our technology and we might not be able to identify and successfully implement an alternative product development strategy.
- If the market opportunities for our product candidates are smaller than we believe they are, our product revenues may be adversely affected and our business may suffer.
- The commercial success of our product candidates 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.

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

- The regulatory approval processes of the U.S. Food and Drug Administration, or FDA, and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable. If we are not able to obtain required regulatory approval for any of our current or future product candidates, our business may be materially and adversely affected.
- Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to post-market study requirements, marketing and labeling restrictions, and even recall or market

withdrawal if unanticipated safety issues are discovered following approval. 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 and may experience difficulties in managing growth.

Risks Related to Our Dependence on Third Parties

- We rely on third parties to conduct, supervise, and monitor our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.

- We are contracting with third parties for the manufacture of components of our product candidates, particularly for commercialization, just as we do to provide materials required for the production of the Optejet and for some of our current research and development activities. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development and 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 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.

- 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.

- 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.

- 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 295 Madison Avenue, Suite 2400, New York, NY 10017, 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 a pre-commercial ophthalmic technology company developing the Optejet® delivery system both for use in combination with our own drug-device therapeutics and for out-licensing for use in combination with therapeutics for additional indications. Our aim is to improve the delivery of topical ophthalmic medication through the ergonomic design of the Optejet which facilitates ease-of-use and delivery of more physiologically appropriate medication volume, with the goal to reduce side effects and improve tolerability, and introduce digital health technology to improve therapy compliance and ultimately medical outcomes.

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, in order to administer medications. Drug is delivered in a microscopic array of droplets faster than the blink reflex to help ensure instillation success. The precise delivery of a low-volume columnar spray by the Optejet® minimizes contamination 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 ~ 50%.

A more physiologically appropriate volume of medication in the range of seven to nine 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. A 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 drugs 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 to provide reminders via Bluetooth to smart devices and date and time stamp device use. 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.

Our drug-device therapeutic programs include MicroPine, MicroLine and Mydcombi™. MicroPine is our first-in-class topical therapy for the treatment of progressive myopia, a back-of-the-eye ocular disease associated with pathologic axial elongation and sclero-retinal stretching. In the United States, myopia is estimated to affect approximately 25 million children, with up to five million considered to be at high risk for progressive myopia. In February 2019, the FDA accepted our investigational new drug application, or IND, to initiate a Phase III registration trial of MicroPine, or the CHAPERONE study, to reduce the progression of myopia in children. The first patient was enrolled in the CHAPERONE study in June 2019. On October 9, 2020, we entered into a license agreement, or the Bausch License Agreement, with Bausch + Lomb, pursuant to which Bausch + Lomb may 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 may receive up to a total of $35.0 million in additional payments, based on the achievement of certain regulatory and launch-based milestones. Bausch + Lomb also will 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, Bausch + Lomb assumed sponsorship of the IND as well as ownership and the costs related to the ongoing CHAPERONE study.

We have also successfully expanded our manufacturing capabilities through a partnership with Coastline International, Inc. located in Tijuana, Mexico, and the construction of our own fill and finish facility in Redwood City, California. As of the date of filing, we are up-to-date supplying clinical product for this study.

MicroLine is our investigational pharmacologic treatment for presbyopia. Presbyopia is 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. Allergan recently launched Vuity™, a pilocarpine drug product for the treatment of presbyopia. Our second Phase III study, VISION-2, used the same drug, delivered with the advantages of the Optejet®. We released positive top-line results from VISION-2 in the fourth quarter of 2022.

Mydcombi™ is our fixed combination formulation of tropicamide-phenylephrine for mydriasis and a novel approach for the over 100 million office-based comprehensive and diabetic eye exams estimated to be performed every year in the United States. We completed two Phase III trials for Mydcombi and announced positive results from these studies, known as MIST-1 and MIST-2, and have submitted a New Drug Application, or NDA, to the FDA seeking approval to market the product in the U.S. In October 2021, we received a complete response letter, or CRL, in response to our NDA, which in part informed us that pre-filled or co-packaged ophthalmic drug dispenser products like Mydcombi have been reclassified as drug-device combination products. This reclassification was based upon the U.S. Court of Appeals for the D.C. Circuit's decision in Genus Medical Technologies v. FDA, not involving Eyenovia, which ordered that products meeting the statutory definition of a device, but were previously classified by the FDA as drugs must be regulated as devices. Before this ruling, the FDA regulated pre-filled or co-packaged ophthalmic dispensers as part of the approved ophthalmic drug distributed and sold with the dispenser. After the ruling, however, the dispenser must be considered as a distinct device constituent part of a drug-device combination product. We resubmitted the NDA on November 8, 2022, and the FDA is currently reviewing our application with a Prescription Drug User Fee Act (PDUFA) target action date of May 8, 2023.

On August 10, 2020, we entered into a license agreement, or the Arctic Vision License Agreement, with Arctic Vision (Hong Kong) Limited, or Arctic Vision, which was amended on September 14, 2021, pursuant to which Arctic Vision may develop and commercialize MicroPine, 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., or Senju. In addition, we may receive up to a total of $39.7 million in additional payments, based on various development and regulatory milestones, including the initiation of clinical research and approvals in Greater China and South Korea, and development costs. Arctic Vision also will purchase its supply of MicroPine, MicroLine and Mydcombi from Eyenovia or, for such products not supplied by Eyenovia, pay a mid-single digit percentage royalty on net sales of such products, subject to certain adjustments. We will pay between 30 and 40 percent of such payments, royalties, or net proceeds of such supply to Senju pursuant to an exclusive license agreement with Senju dated March 8, 2015, as amended.

We are in active discussions with manufacturers of existing and late-stage ophthalmic medications to explore whether development with the Optejet technology can solve unmet medical and business needs. Some of those business needs could include extension of exclusivity under the Optejet patents, improvement in a drug's tolerability profile, or potential improvement in treatment compliance.

The following summarizes our product pipeline and anticipated milestones:

Product Candidate	Indication	Next Expected Milestones
MicroLine	Improvement in Near Vision (Presbyopia)	Pre-NDA meeting April 2023
MicroPine	Pediatric Myopia Progression (Near-Sightedness)	Phase III CHAPERONE IND transferred to Bausch + Lomb
Mydcombi	Pharmaceutical Mydriasis (Pupil Dilation)	Potential FDA approval date May 8, 2023

Our Strategy

Our goal is to become a leading developer and provider of advanced ophthalmic therapies based upon our microdose array print (MAP) platform technology and digital health platform for interactive patient care. These unique products would be commercialized by us and/or our partners globally. The key elements of our strategy to achieve this goal are:

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 reduces 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 our pipeline of patented micro-therapeutic product

candidates is 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, improved side effect profile and enhanced patient experience with the Optejet as compared to conventional eye drops.

Leverage our electronic, smartphone-enabled "e-health" technology to introduce and develop patient-specific compliance monitoring program. The Optejet's mobile e-health technology 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 independently or 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.

Develop therapeutic solutions for ophthalmic conditions with high unmet needs and no approved therapy. We plan to target chronic ophthalmic conditions with a high unmet medical need. By leveraging our piezo-print microdosing technology, we aim to reach conditions where there are no approved drug therapies. For example, our MicroPine program involves a proprietary formulation of low-dose atropine intended to slow myopia progression in the pediatric population. There are currently no commercially-available medical therapies in the United States to treat this indication.

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 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.

Mydcombi contains tropicamide and phenylephrine. However, as demonstrated in our two Phase III studies for this product candidate, patients administering Mydcombi reported few ocular adverse events and no systemic adverse events when they administered our microdosed product candidate. Compared with historical data for traditional eye drops, Mydcombi appeared to be much better tolerated, with low systemic absorption of phenylephrine alone.

With the Optejet platform technology, we believe that the known adverse event profile of pilocarpine, including headaches, also may be moderated to make MicroLine the preferred choice for presbyopia over other potential pilocarpine drop options. The same is true with MicroPine, where we believe that microdosing may result in a better tolerated product for children using topical ophthalmic atropine.

Our Solution: The Optejet

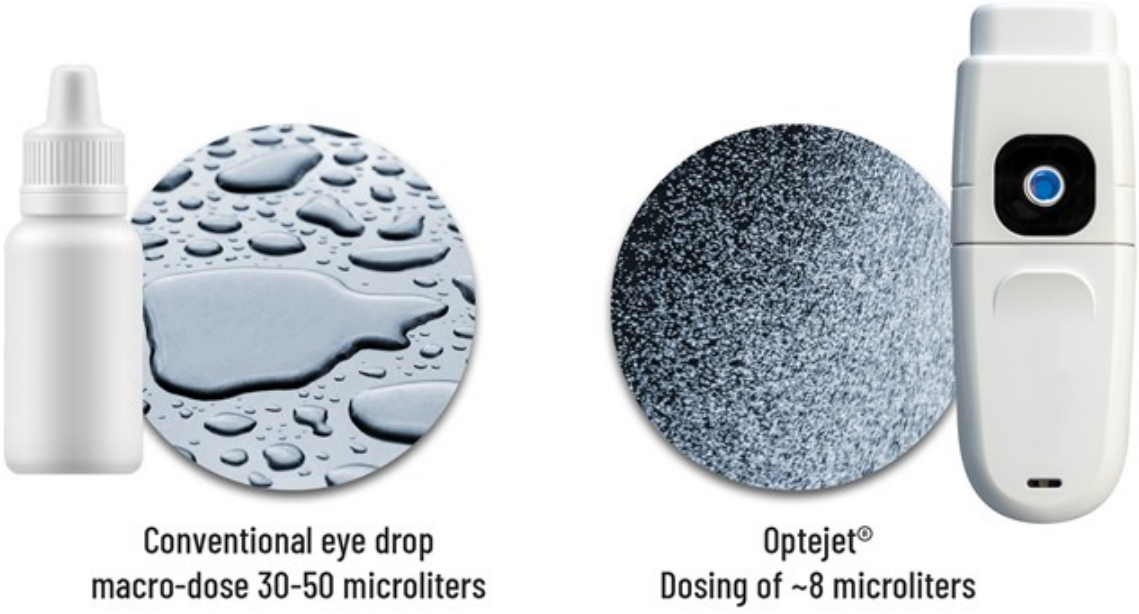
The Optejet dispenser delivers doses of approximately 7-9 µL, directly coating the corneal surface where 80% of intraocular drug penetration occurs. We believe that microdosing may reduce drug and toxic preservative exposure by more than 75%, thus reducing ocular irritation, and resulting in potentially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

We believe that we are one of the only companies with clinical stage technology for targeted microdosing of ophthalmic investigational therapies having fully completed the Phase III clinical studies needed and made an NDA submission. The Optejet is based on MAP, 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.

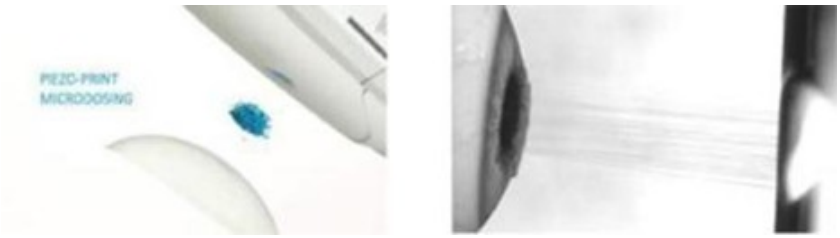
The FDA has determined that our products will be treated as combination drug/device products, with CDER as the lead reviewing center. As such, we do not anticipate needing separate FDA approval for the Optejet dispenser alone.

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.

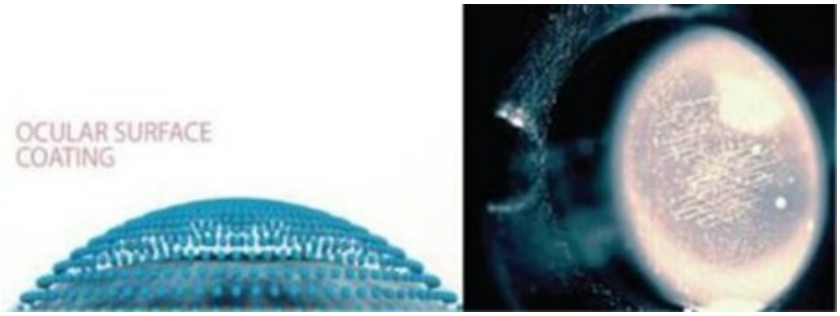


Targeted dose instillation: The Optejet allows for targeted delivery to the ocular surface and cornea, avoiding the conjunctival cul-de-sac. The micro-jet spray created by the piezo-electric vibrations is columnated and focused to provide accurate delivery to the corneal surface where the majority of 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 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.



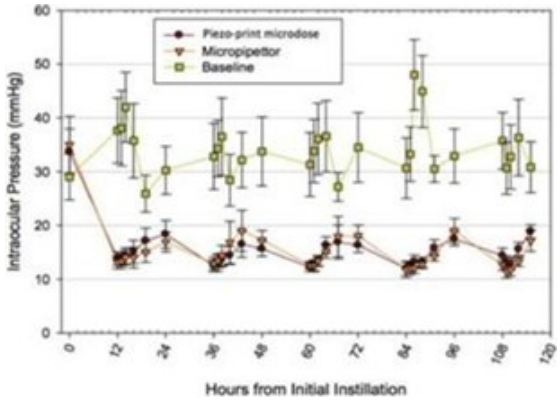
Smart electronics: A key feature of the Optejet is the embedded electronic, Bluetooth enabled "e-health" system, which we believe is the first intelligent electronic delivery system for ophthalmic therapies. Our electronic functions are designed to enable patients and physicians to track when doses are 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 now provide a way for healthcare providers to bill for this important service.

Clinical Trial Results

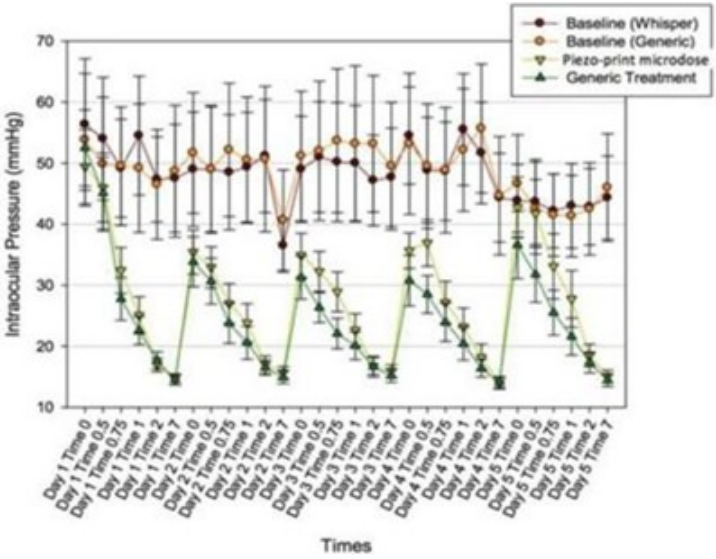
We have an established platform for microdose administration of ophthalmic solutions. Our preclinical and clinical studies suggest that a microdose of approximately 8 µL of medication results in clinical efficacy comparable to that of traditional eye drops, with the advantages of fewer ocular side effects 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



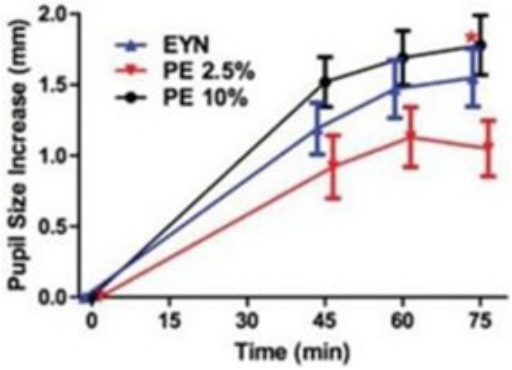
IOP Lowering Effect of Micro-Therapeutic Dose of Latanoprost in Canine Model



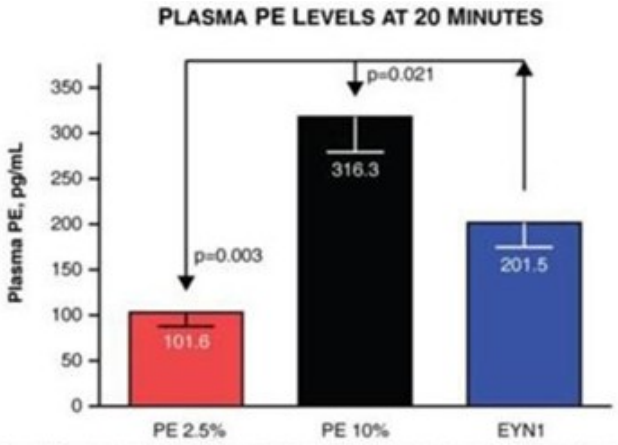
The Phase II EYN-1601 clinical trial compared the mydriatic effect of phenylephrine 10% microdosed (~7 µL in volume) with the Optejet (EYN) to phenylephrine 10% (PE 10%) and phenylephrine 2.5% (PE 2.5%) eye drops (each ~32 µL in volume) in 24 eyes. At 75-minute peak dilation, our microdose provided similar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



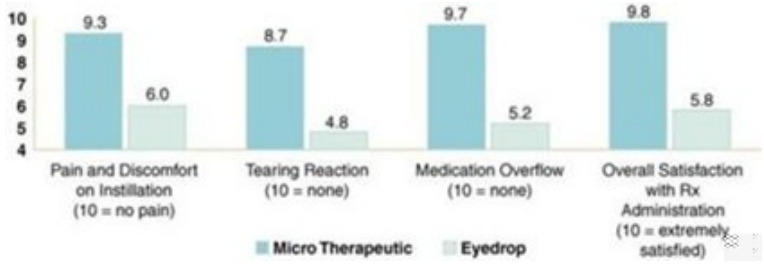
Plasma free PE concentration in venous blood drawn 20 minutes after ocular topical drug administration. Circulating PE was highest in PE 10% subjects (316.3±36.8 pg/mL), and was significantly 36.3% lower in EYN subjects (201.5±27.1 pg/mL; p=.021). Plasma PE was significantly lower in PE 2.5% subjects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

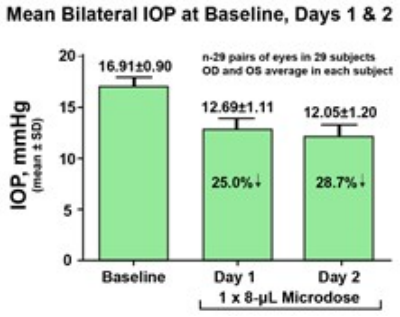
Adverse Event Description	PE 10% (Eyedrops)	EYN (PE 10% microdose)
Ocular blurriness	1	0
Ocular burning/stinging/irritation	4	1
Ocular dryness	2	0
Subtotal by Treatment Group	7	1

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.



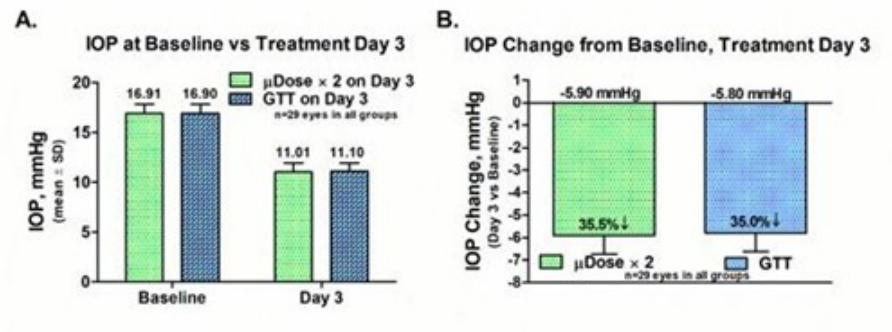
In 2018, Eyenovia completed a third early phase trial (EYN-POC-PG-21) to extend the findings of the two previous trials evaluating Optejet administration of mydriatic agents. This study was a single-center, open-label, prospective, crossover design evaluating the usability, patient tolerability, and 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.

Our Product Candidates

Eyenovia is currently focused on three programs: MicroLine (for presbyopia), MicroPine (for progressive myopia) and Mydcombi (for mydriasis).

MicroLine

MicroLine is our 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 Benozzi et al, 2012, 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. With MicroLine, we plan to introduce 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 are evaluating whether topical ocular microdosing of pilocarpine using the Optejet dispenser in presbyopic individuals can effectively improve near vision without compromising distance vision and without causing the undesirable side effects of traditionally administered pilocarpine. 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. The results of VISION-1 and VISION-2 are being presented to the FDA in a pre-NDA meeting scheduled for April 2023.

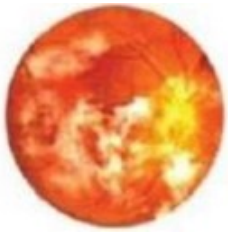
MicroPine

A key therapeutic program for Eyenovia is our first-in-class topical treatment for progressive myopia, a back-of-the-eye disease.

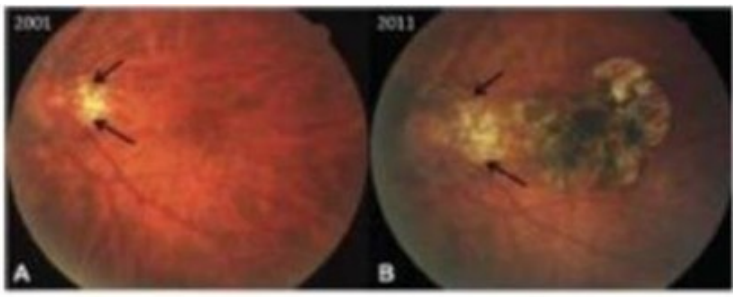
Background of Progressive Myopia and Market Opportunity

Myopia is an ocular disorder that results in blurry vision when looking at distant objects. This happens when the eyeball is too long or corneal curvature is too steep causing light entering the eye to be incorrectly focused. Myopia is one of the most common refractive errors seen in children. Myopia that is present in young children tends to increase through the school years. As myopia progresses, so does the risk of retinal detachment, cataracts, myopia maculopathy and even blindness. It is estimated that over 25 million children in the United States suffer from progressive myopia, with approximately 5 million children being at high risk.

Examples of Retinal Changes Due to Myopia



Progressive Myopia with Retinal Atrophy Changes



While currently there are no FDA-approved therapies for myopia progression, there is growing evidence of the therapeutic benefit of topical atropine ophthalmic solution, an anticholinergic agent used for pupil dilation and treatment of lazy eye, as a treatment to slow progression. Academic groups have demonstrated that low dose atropine solution reduces myopia progression 60-70%, with sustained effect through three years. A recent therapeutic evidence assessment and review by the American Academy of Ophthalmology, indicates Level 1 (highest) evidence of efficacy for low dose atropine for reduction of progressive myopia (Ophthalmology 2017;124:1857-1866; Ophthalmology 2016; 123(2) 391:399). While atropine 1% ophthalmic solution is FDA-approved and commercially available in the United States for pupil dilation and treatment of lazy eye, commonly reported side effects such as burning and stinging during drop administration, and blurred vision and light sensitivity associated with its use make it undesirable for the

treatment of progressive myopia in the pediatric population, thus impeding the drug's clinical utility and adoption for myopia progression.

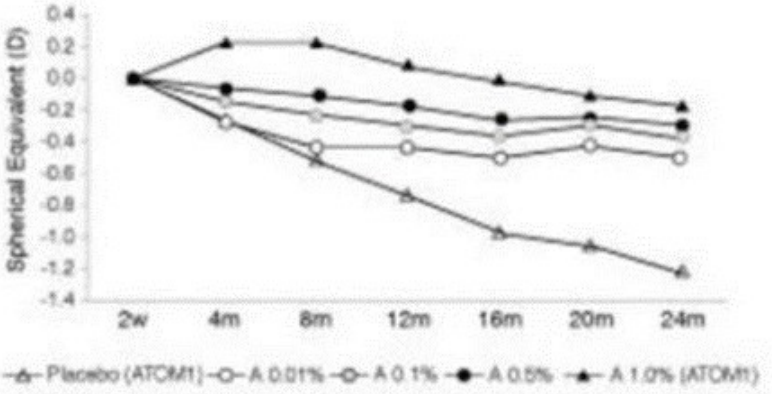


Figure 2. Mean change in spherical equivalent for groups from baseline, 2 weeks, and 4 to 24 months with atropine 0.01%, 0.1%, and 0.5% from the ATOM2 study, and placebo and atropine 1.0% from the ATOM1 study. A = atropine; ATOM = Atropine for the Treatment of Myopia; D = diopter; m = month; w = week.

Our MicroPine program involves the development of a micro-formulation (dilute and low volume) of atropine ophthalmic solution for reduction of myopia progression in children.

Phase III Clinical Development Program

The FDA accepted Eyenovia's IND to initiate our single Phase III registration trial of MicroPine (the CHAPERONE study) to reduce the progression of myopia in children. Eyenovia enrolled its first patient in the CHAPERONE study in June 2019. The trial is a U.S.-based, multi-center, randomized, double-masked study enrolling more than 400 children and adolescents. Participants will be equally randomized to receive nightly treatment with either of two MicroPine treatment concentrations or a placebo control arm. The primary assessment of efficacy is based on reduction in myopia progression after 3 years of medication use. The IND and responsibility for the CHAPERONE study have been transferred to Bausch + Lomb, who is responsible for the FDA filing strategy.

Mydcombi

Mydcombi is a unique fixed combination micro-formulation product candidate for mydriasis (eye dilation) intended to facilitate the over 100 million estimated office-based comprehensive and diabetic eye exams and four million ophthalmic surgical dilations performed every year in the United States. Our fixed combination product candidate has been developed to facilitate efficient pupil dilation with the potential to reduce unintended effects of conventionally administered mydriatic agents. We believe the market for Mydcombi exceeds $250 million in the United States alone.

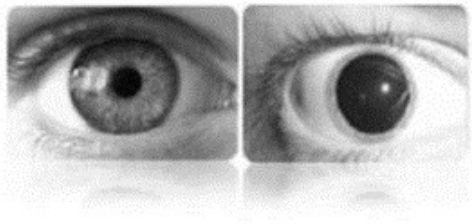
Background of Mydriasis and Market Opportunity

There are over an estimated one hundred 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, if approved, will allow 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 two separate topical pharmacologic agents/drops be administered sequentially (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%.

With millions of patients exposed to mydriatic pharmacologic agents every year, we are developing a microdose alternative whereby the Optejet can be deployed to reduce ocular and systemic exposure by more than 75%. This potential improvement stems from lowering the dose from the 30–50 µL in standard drops to just 8 µL with MicroStat combined with targeted delivery to the ocular surface. We expect to achieve similar mydriatic activity as drops without the high incidence of unwanted side effects.

Pharmacologic mydriasis: dilated pupil after application



Phase III Clinical Development Program

We completed the Phase III clinical trials of fixed-combination tropicamide 1% and phenylephrine 2.5% administered using the Optejet for mydriasis in November 2019.

The MicroStat program consisted of two Phase III randomized, controlled, cross-over clinical studies evaluating pupil dilation with our fixed combination product (MicroStat) in comparison with the individual drug components (phenylephrine 2.5% and tropicamide 1%, respectively) (the MIST-1 study), and with a placebo (the MIST-2 study). The primary endpoint for each study was the mean change in pupil diameter at 35 minutes post-drug administration.

The MIST-1 study was a double-masked, active-controlled, three-period cross-over superiority study evaluating MicroStat ophthalmic solution versus the two individual drug components contained in MicroStat (phenylephrine 2.5% and tropicamide 1% ophthalmic solutions). All study drugs were administered using the Optejet.

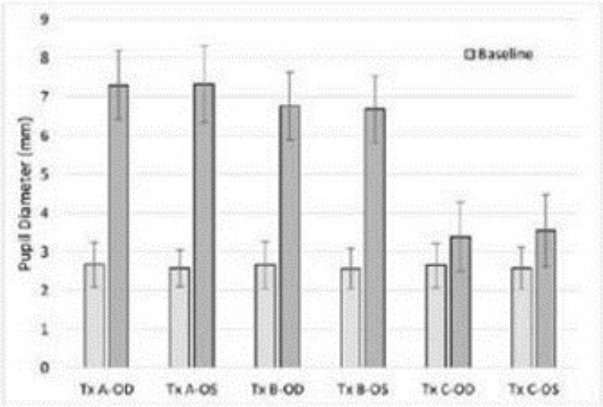
Volunteer participants were evaluated for study eligibility during a screening visit and enrolled after providing study consent. Subjects meeting all inclusion/exclusion criteria were scheduled for three treatment visits, which occurred at least two days, but no more than seven days apart. At each treatment visit, baseline measurements were taken, then one of the three study drugs was administered to both eyes in two separate instances, approximately five minutes apart. Afterwards, efficacy and safety assessments were performed at specific time intervals, including pupil diameter measured by digital pupillometry in highly photopic conditions established by using a fully-charged transilluminator at the brightest setting. Subjects were equally randomized to receive all three treatments according to one of the six possible sequences of study drug administration.

The MIST-1 study was double-masked so that there were no differences in drug presentation. Study drug administration was performed by seven different trained personnel during the trial. To maintain masking, personnel who administered study drug were not allowed to perform post-drug administration ophthalmic assessments.

A total of 64 subjects were randomized to receive the study drug. Two subjects withdrew after the first treatment visit; therefore, the resulting per-protocol analysis population consisted of 62 subjects (124 eyes). Mean pupil diameter for each eye at baseline and at 35 minutes post-drug administration is shown graphically below. At 35 minutes, the treatment group difference between MicroStat and

tropicamide 1% was 0.440 mm (SE 0.1839), which was statistically significant (p = 0.0183). The treatment group difference between MicroStat and phenylephrine 2.5% at the same timepoint was 3.638 mm (SE 0.1817), which was also statistically significant (p <0.0001). Since the null hypothesis was rejected for both sets of comparisons, the primary endpoint was met.

Pupil Diameter by Treatment at Baseline and 35 Minutes
(PP Population)



Mean ± Standard Deviation
Tx A = phenylephrine 2.5%-tropicamide 1%; Tx B = tropicamide 1%; Tx C = phenylephrine 2.5%.

As shown below, at 35 minutes post-drug administration, Mydcombi achieved a clinically meaningful pupil diameter ≥ 6.0 mm in 95.2% of right eyes and 93.5% of left eyes compared to a lower proportion for tropicamide 1% (79.0% and 77.4% of right and left eyes, respectively) and for phenylephrine 2.5% (1.6% for both right and left eyes). Mydcombi also achieved a pupil diameter ≥ 7.0 mm in 67.7% of right and left eyes compared to a lower proportion for tropicamide 1% (43.5% and 41.9% or right and left eyes, respectively) and for phenylephrine 2.5% (0% for right and left eyes).

Proportion of Eyes Achieving Pupil Diameter ≥ 6.0 mm and ≥ 7.0 mm at 35 Minutes
(PP Population)

35 Min Post Dose	Mydcombi		Tropicamide 1%		Phenylephrine 2.5%	
Combined Visits (1, 2, 3)	OD (N=62)	OS (N=62)	OD (N=62)	OS (N=62)	OD (N=62)	OS (N=62)
Pupil diameter ≥ 6.0 mm	59 (95.2)%	58 (93.5)%	49 (79.0)%	48 (77.4)%	1 (1.6)%	1 (1.6)%
Pupil diameter < 6.0 mm	3 (4.8)%	4 (6.5)%	13 (21.0)%	14 (22.6)%	61 (98.4)%	61 (98.4)%
Pupil diameter ≥ 7.0 mm	42 (67.7)%	42 (67.7)%	27 (43.5)%	26 (41.9)%	0	0
Pupil diameter < 7.0 mm	20 (32.3)%	20 (32.3)%	35 (56.5)%	36 (58.1)%	62 (100.0)%	62 (100.0)%

The rate of treatment emergent adverse events, or TEAEs, was low, and consistent with those observed with commercially available dilating eye drops (e.g. blurry vision and stinging). Two TEAEs were reported in the MicroStat eyes, while four TEAEs were reported in each of the other two treatment groups. All events were mild in nature. No non-ocular adverse events were reported.

The MIST-2 Study was a multi-center, double-masked, placebo-controlled, three-period crossover superiority study evaluating MicroStat ophthalmic solution versus placebo. Both study drugs were administered using the Optejet.

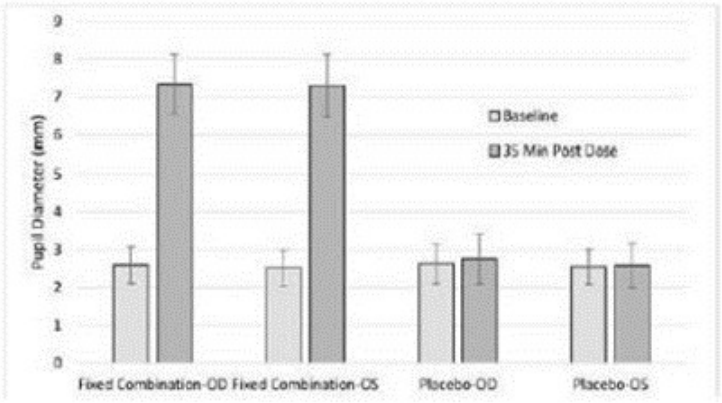
Volunteer participants were evaluated for study eligibility during a screening visit and enrolled after providing study consent. Subjects meeting all inclusion/exclusion criteria were scheduled for three treatment visits, which occurred at least two days, but no more than seven days apart. A two-sequence, three-period crossover design was used. At each treatment visit, baseline measurements were taken, then either the investigational drug or the placebo was administered to both eyes in two separate instances, approximately five minutes apart. Only one study drug was administered per treatment visit, and subjects were equally randomized to one of two sequences,

ABB and BAA, where A was the Eyenovia fixed combination and B was placebo. Afterwards, efficacy and safety assessments were performed at specific time intervals, including pupil diameter measured by digital pupillometry in highly photopic conditions established by using a fully-charged transilluminator at the brightest setting.

Like MIST-1, this study was double-masked so that there were no differences in drug presentation. Study drug administration was performed by five different trained personnel and, to maintain masking, personnel who administered study drug were not allowed to perform post-drug administration ophthalmic assessments.

A total of 70 subjects at two investigational sites were randomized to receive study drug. One subject withdrew after the first treatment visit; therefore, the resulting per-protocol analysis population consisted of 69 subjects (138 eyes). Mean pupil diameter for each eye at baseline and at 35 minutes post-drug administration is shown graphically below. At 35 minutes, the treatment group difference between Mydcombi and placebo was 4.63 mm (SE 0.0544), which was highly statistically significant ($p < 0.0001$); consequently, the null hypothesis was rejected and the primary endpoint was met.

Pupil Diameter by Eye and Treatment at Baseline and 35 Minutes
(PP Population)



Mean ± Standard Deviation

As shown in the table below, at 35 minutes post-drug administration, Mydcombi achieved a clinically meaningful pupil diameter ≥ 6.0 mm in 92.8%% of right eyes and 94.2% of left eyes and pupil diameter ≥ 7.0 mm in 69.6% of right and 68.1% of left eyes. None of the eyes in the placebo group achieved similar dilation.

Proportion of Eyes Achieving Pupil Diameter ≥ 6.0 mm and ≥ 7.0 mm at 35 Minutes
(PP Population)

35 Min Post Dose	Mydcombi		Placebo	
Combined Visits (1, 2, 3)	OD (N=69)	OS (N=69)	OD (N=69)	OS (N=69)
Pupil diameter ≥ 6.0 mm	64 (92.8)%	65 (94.2)%	0	0
Pupil diameter < 6.0 mm	5 (7.2)%	4 (5.8)%	69 (100.0)%	69 (100.0)
Pupil diameter ≥ 7.0 mm	48 (69.6)%	47 (68.1)%	0	0
Pupil diameter < 7.0 mm	21 (30.4)%	22 (31.9)%	69 (100.0)%	69 (100.0)

Two TEAEs (one event of mild instillation site pain and one event of moderate photophobia) were reported in the Mydcombi group, while none were reported with the use of placebo. No non-ocular adverse events were reported. Essentially pain-free mydriasis was achieved without the use of a topical anesthetic, which is often the practice.

The outcomes of MIST-1 and MIST-2 are consistent. As shown below, in both studies, Mydcombi achieved a mean change in pupil size between 4.6 mm and 4.8 mm at 35 minutes post-dose. In both studies, between 93% and 95% of eyes treated with the fixed

combination mydriatic drug achieved a pupil diameter ≥ 6.0 mm at this same timepoint. Additionally, in MIST-1, the median time to maximum post-baseline pupil diameter with ≥ 1.0 mm increase from baseline for fixed combination solution was 73.0 minutes, while in MIST-2, it was 71.0 minutes.

Efficacy of Mydcombi in MIST-1 and MIST-2 Studies (PP Populations)

	MIST-1	MIST-2
Mean change in pupil diameter from baseline at 35 minutes	4.6 mm right eyes 4.7 mm left eyes	4.7 mm right eyes 4.8 mm left eyes
Proportion of eyes with pupil diameter ≥ 6.0 mm at 35 minutes	95.2% of right eyes 93.5% of left eyes	92.8% of right eyes 94.2% of left eyes
Median time to maximum post-baseline pupil diameter with ≥ 1.0 mm increase from baseline	73.0 minutes	71.0 minutes

The consistency of these results validates the robustness of the study designs and demonstrates the impressive treatment effect of Mydcombi. More generally, these outcomes serve to further validate the bioavailability and efficacy of Optejet drug administration to the ocular surface.

With the primary objectives of our Phase III clinical program met, in December 2020, we submitted an NDA to the FDA for marketing approval in the United States. In October 2021, we received a CRL in response to our NDA, which in part informed us that pre-filled or co-packaged ophthalmic drug dispenser products like Mydcombi have been reclassified as drug-device combination products. This reclassification was based upon the U.S. Court of Appeals for the D.C. Circuit's decision in Genus Medical Technologies v. FDA, not involving Eyenovia, which ordered that products meeting the statutory definition of a device but were previously classified by the FDA as drugs must be regulated as devices. Before this ruling, the FDA regulated pre-filled or co-packaged ophthalmic dispensers as part of the approved ophthalmic drug distributed and sold with the dispenser. After the ruling, however, the dispenser must be considered as a distinct device constituent part of a drug-device combination product. As a result, we resubmitted the NDA on November 8, 2022, and announced on December 13, 2022 that the FDA has accepted the resubmission. The FDA has assigned the resubmitted NDA a standard review with a Prescription Drug User Fee Act (PDUFA) target action date of May 8, 2023.

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.

Sales and Marketing

We are taking a staged approach to the commercialization of our products, retaining rights for Mydcombi to potentially optimize the introduction of the technology to the market, and establishing partnerships with licensees for products that require a larger investment in terms of sales force and distribution. Our management team and directors, which are leading the commercialization planning of our lead product candidates in the United States, have substantial experience in the commercialization of ophthalmic therapeutics.

Mydcombi is our first expected commercial product. Mydcombi is a cash-pay pharmaceutical supply, administered and purchased by clinics and doctors for in-office use. The cost of the product is folded into the established reimbursement for the comprehensive eye exam and thus lends itself to a single specialty-pharmacy distribution model without the need for formulary negotiations and contracting at the managed care level. As such, we estimate Mydcombi sales and marketing costs will be significantly below that of a conventional prescription-based pharmaceutical product. As a highly differentiated product with meaningful benefits for both providers and patients, we anticipate fast adoption, especially because part of our strategy is to maintain good economics for the practice. Lastly, we believe that we can be successful with a limited in-person sales force as we are not aware of any active competition in this space.

MicroLine is our second expected product for commercialization. Like Mydcombi, MicroLine would also be “cash-pay,” negating the need for infrastructure focused on managed care reimbursement. We currently have licensed MicroLine as well as Mydcombi to Arctic Vision for development and commercialization in Greater China and South Korea. Unless we establish additional partnerships for MicroLine, we plan to expand our sales force from approximately ten to fifty people in the United States and focus on promotion in the optometrist office. We also plan to leverage the experience that these offices have had with Mydcombi to speed acceptance and prescribing of MicroLine to appropriate patients.

MicroPine is our third expected product for commercialization. MicroPine is a more standard therapeutic, likely reimbursed by payers after negotiating for formulary position. We have licensed MicroPine to Arctic Vision in Greater China and Korea, and to Bausch Health in the United States and Canada. In both cases, our licensee will be responsible for commercialization within their own sales and marketing structures.

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 commissioning a facility located in Redwood City, CA. The facility is dedicated to the fill and finish for Eyenovia’s proprietary primary closure container, which is used in its different therapies, as well as assembly and final packaging of cartridges. Redwood City came on-line with the production of clinical materials in mid-2022.

Base units are manufactured by Eyenovia at its Reno, NV engineering center.

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 MicroLine, Allergan has launched Vuity, a pilocarpine eye drop for the treatment of presbyopia. Along with Allergan, there are other pharmaceutical companies developing therapies for presbyopia, none of which makes use of microdosing technology or deliver medication as a spray.

We expect that both Mydcombi and MicroLine would be “cash pay” products, as Mydcombi is purchased directly by offices and used routinely in eye exams, and MicroLine would be considered an “aesthetic” prescription product not generally covered by third party insurance.

For MicroPine, we are not aware of any FDA-approved drugs to slow the progression of myopia. There are other versions of traditional eye drop atropine under development by other pharmaceutical companies for this indication. There also are versions of compounded topical atropine that have not been tested for their safety or efficacy that are dispensed on an individual basis to patients.

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.

The Company is currently engaged in three inter partes review, or IPR, proceedings challenging the validity of certain patents owned by Sydnexis, Inc. The IPRs are as follows: IPR2022-00384, filed on December 29, 2021, challenging U.S. Patent No. 10,842,787; IPR2022-00414, filed on January 7, 2022, challenging U.S. Patent No. 10,940,145; and IPR2022-00415, filed on January 7, 2022, challenging U.S. Patent No. 10,888,557. All three IPRs were instituted by the Patent Trial and Appeal Board. Final decisions in each of these proceedings are expected on or before July 15, 2023.

Patents

As of December 31, 2022, we owned eighteen U.S. issued and allowed utility patents or design patents, and eight pending U.S. patent applications, as well as 89 issued foreign patents, and 33 pending foreign patent applications, and one pending international PCT application.

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™, 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 and MicroLine 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 30, 2023, we had 41 total employees. All 41 are full-time employees and there are no part-time employees. We also engage various consultants and contractors.

We consider our relations with our employees to be good. To successfully commercialize our product candidates, we must be able to attract and retain highly skilled personnel. We anticipate hiring additional employees during 2023. We continually evaluate the business need and opportunity and balance in-house expertise and capacity with outsourced expertise and capacity. Currently, we outsource substantial clinical trial work to clinical research organizations and manufacturing to contract manufacturers.

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 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
Tsontcho Ianchulev, M.D., M.P.H.	Chairman and Director of Eyenovia
Rachel Jacobson	Director of Eyenovia and President of the Drone Racing League (DRL)
Charles Mather	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 and Director of Eyenovia
John Gandolfo	Chief Financial Officer and Secretary of Eyenovia
Bren Kern	Chief Operating Officer of Eyenovia

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 might not be able to continue as a going concern, which would likely cause our stockholders to lose most or all of their investment.

Our audited financial statements for the year ended December 31, 2022 were prepared under the assumption that we would continue as a going concern. However, we have concluded that there is substantial doubt about our ability to continue as a going concern, therefore 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, 2022, indicating that, without additional sources of funding, our cash at December 31, 2022 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, however, management cannot assure you that its plans will be successful. If we cannot continue as a viable entity, our stockholders would likely lose most or all of their investment in us.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and its financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank, or SVB, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each placed into receivership. Although a statement by the Department of the Treasury, the Federal Reserve and the FDIC stated that all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, Signature Bank or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder. If any of our counterparties to any such instruments were to be placed into receivership, we may be unable to access such funds. In addition, if any parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. In this regard, counterparties to SVB credit agreements and arrangements, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts from the closure of SVB and uncertainty remains over liquidity concerns in the broader financial services industry. Similar impacts have occurred in the past, such as during the 2008-2010 financial crisis. We do not currently have funds deposited with SVB in excess of the FDIC insurance limit.

Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U.S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. There is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following:

- Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- Loss of access to revolving existing credit facilities or other working capital sources and/or the inability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources;

- Potential or actual breach of contractual obligations that require us to maintain letters or credit or other credit support arrangements; or

- Termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by parties with whom we conduct business, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. For example, a party with whom we conduct business may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy. Any bankruptcy or insolvency, or the failure to make payments when due, of any counterparty of ours, or the loss of any significant relationships, could result in material losses to us and may material adverse impacts on our business.

We will need to raise additional capital in order to continue developing our product candidates and to manufacture and commercialize them. Such funding might not be available on acceptable terms, or at all. Failure to obtain this necessary capital may force us to delay, limit or terminate certain of our product development and commercialization efforts or to continue operations.

We require substantial additional funding to continue our research and development activities. We also need substantial funding to advance potential manufacturing and commercialization, and fund our operating expenses and other activities into next year. If additional capital is not available when needed, including because of general market conditions, we may need to significantly scale back or reprioritize our research and development activities, manufacturing and commercialization plans, and potentially even cease our operations.

We will require substantial funds to discover, develop, protect and conduct research and development for our product candidates, including preclinical testing for future product candidates and clinical trials of any of our product candidates, and to potentially manufacture and market any such product that may be approved for commercial sale. Even if we are successful in raising additional capital, such funds may prove to be insufficient for these activities. Our financing needs may change substantially because of research and development, manufacturing and commercialization-related costs, competition, clinical trials and costs arising from additional regulatory approvals. We might not succeed in raising needed additional funds. The timing of our need for additional funds will depend on a number of factors, which factors are difficult to predict or may be outside of our control, including:

- the resources, time and costs required to initiate and complete research and development, to initiate and complete preclinical studies and clinical trials and to obtain regulatory approvals for our product candidates;

- progress in our research and development programs;

- the timing, receipt and amount of milestone, royalty and other payments from any current or future collaborators, if any; and

- costs necessary to protect our intellectual property.

If our estimates and predictions relating to any of these factors are incorrect, we may need to modify our operating plan. Additional funds might not be available to us on acceptable terms, or at all, when needed.

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

Until such time as we can generate substantial product revenues, as to which we can make no assurance, we intend to finance our cash needs through equity offerings, debt financings, government and/or other third-party grants or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. 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 one or more clinical research or development programs 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, research programs or product candidates, or grant licenses on terms that might not be favorable to us.

The terms of the Loan and Security Agreement with Avenue Capital Management II, L.P. and the lenders listed therein 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 a Loan and Security Agreement with Avenue Capital Management II, L.P. and related entities (together, "Avenue") that is secured by a lien on all of our assets. 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 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 $118.2 million since inception, have not generated any product sales revenue and have not achieved profitable operations. Our net losses were approximately $28.0 million and $12.8 million for the years ended December 31, 2022 and 2021, 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. It could be a year or more, if ever, before we have a commercialized product. 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 the ongoing development of our product candidates;
- seek marketing approvals for our current and future product candidates that successfully complete clinical trials;
- continue to develop a sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval;
- develop, maintain, expand and protect our intellectual property portfolio;

- implement additional operational, financial and management systems;
- attract, hire and retain additional administrative, clinical, regulatory and scientific personnel; and
- initiate preclinical studies and clinical trials for any additional product candidates that we may pursue in the future.

Even if we are able to generate revenues from the sale of our potential products, 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, expand our business or continue our operations. In addition, because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability.

Our relatively short operating history may make it difficult for investors to evaluate the success of our business to date and to assess our future viability.

We are a clinical stage company, which commenced active operations in 2014. Our operations to date have been primarily limited to organizing and staffing our company, business planning, raising capital and developing our product candidates. We have entered into licensing agreements with Bausch Health, for the development and commercialization of MicroPine in the United States and Canada, Arctic Vision, for the development and commercialization of MicroPine, MicroLine and Mydcombi™ in Greater China and South Korea, and Senju, for the development and commercialization of MicroPine, MicroLine and Mydcombi in Asia (other than Greater China and South Korea). We also submitted an NDA for Mydcombi for pharmacologic mydriasis and initiated our Phase III VISION studies for presbyopia. However, we have not yet demonstrated our ability to obtain marketing approval, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. We will need to transition from a company with a product development focus to a company capable of supporting commercial and manufacturing activities in the near future. We might not be successful in such a transition. In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors during such transition. Consequently, any predictions about our future success or viability might not be as accurate as they could be if we had a longer operating history.

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, 2022, we had federal net operating loss carry-forwards of approximately $85.9 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 DEVELOPMENT AND COMMERCIALIZATION OF OUR PRODUCT CANDIDATES

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

We currently have no products approved for sale and have invested a significant portion of our efforts and financial resources in the development of Mydcombi for mydriasis, MicroPine for pediatric progressive myopia, and MicroLine for presbyopia. Our prospects are substantially dependent on our and our licensees abilities to develop, obtain marketing approval for and successfully commercialize these product candidates.

The success of our product candidates will depend on, among other things, our ability to successfully complete clinical trials of each product candidate. Although we have completed multiple Phase II and III studies for our product candidates, including the MIST-1 and MIST-2 Phase III trials for Mydcombi, and the VISION-1 and VISION-2 Phase III trials for MicroLine, the clinical trial process is uncertain, and failure of one or more clinical trials can occur at any stage of testing.

In addition to the successful completion of clinical trials, the success of our product candidates will also depend on several other factors, including the following:

- receipt of marketing approvals from the FDA or other applicable regulatory authorities;
- establishment of supply arrangements with third-party raw materials suppliers and manufacturers;
- establishment of arrangements with third-party manufacturers to obtain finished drug products that are appropriately packaged for sale;
- the performance of our future collaborators for one or more of our product candidates, if any;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- obtaining and maintaining patent, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protection of our rights in our intellectual property portfolio;
- launch of commercial sales if and when our product candidates are approved;
- a continued acceptable safety profile of our product candidates following any marketing approval;
- commercial acceptance, if and when approved, by patients, the medical community and third-party payors;
- establishing and maintaining pricing sufficient to realize a meaningful return on our investment; and
- competition with other products.

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

Delays in the commencement or completion of clinical testing of product candidates we are developing or may develop in the future may occur and could result in significantly increased costs and longer timelines and could impact our ability to ever become profitable.

The tests and clinical trials of product candidates we develop may not commence, progress or be completed as expected, and delays could significantly impact our product development costs and timelines, as well as a product candidate's market potential, if ultimately approved. The timing of initiation, conduct and completion of clinical trials and other testing of our product candidates may vary dramatically due to factors within and outside of our control and is difficult to predict accurately. We may make statements regarding anticipated timing for commencement, completion of enrollment, and/or availability of results from our clinical studies, but those statements are predictions based on a number of significant assumptions and the actual timing of achievement of development milestones may differ materially from our predictions for a variety of reasons.

Commencement of planned clinical studies may be delayed if we do not secure adequate capital. In addition to lack of adequate capital, commencement and/or completion of these studies may be delayed, terminated or suspended as a result of the occurrence of any of a number of other factors, including the need to obtain authorizations from the FDA and the institutional review boards, or IRBs, of prospective clinical study sites, delayed or inadequate supply of our product candidates or other clinical trial material, slower than expected rates of patient recruitment or enrollment, other factors described below, and unforeseen events.

The commencement of clinical trials of our product candidates can be delayed for many reasons, including delays in:

- obtaining required funding;
- obtaining guidance or authorizations from the FDA or foreign regulatory authorities;
- finalizing the trial design as a result of discussions with the FDA, other regulatory authorities or prospective clinical trial investigators or sites;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- obtaining sufficient quantities of our product candidates and other clinical trial material; or
- obtaining IRB approval to conduct a clinical trial at a prospective site.

In addition, once a clinical trial has begun, it may experience unanticipated delays or be suspended or terminated by us, an IRB, the FDA or other regulatory authorities due to several factors, all of which could impact our, or our licensees', ability to complete clinical trials in a timely and cost-efficient manner, including:

- lack of adequate funding;
- failure to conduct the clinical trial in accordance with regulatory or IRB requirements;
- slower than expected rates of subject recruitment and enrollment;
- higher than anticipated participant drop-out rates;
- failure of clinical trial subjects to use the product as directed or to report data as per trial protocols;
- inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- failure to achieve certain efficacy and/or safety standards;
- subjects experiencing severe side effects or other adverse events related to the investigational treatment;

- delayed or insufficient supply of clinical trial material or inadequate quality of such materials;
- failure of our CROs or other third-party contractors to meet their contractual obligations to us in a timely manner, or at all; or
- delays in quality control/quality assurance procedures necessary for study database lock and analysis of unblinded data.

Significant clinical trial delays also could jeopardize our ability to meet obligations under agreements under which we license our rights to our product candidates, allow other companies to bring competitive products to market before we do, shorten any period of market exclusivity we may otherwise have under our patent rights, and weaken our negotiating position in discussions with potential collaborators, any of which could impair our ability to successfully commercialize our product candidates, if ultimately approved. Any significant delays in commencement or completion of clinical trials of our product candidates, or the suspension or termination of a clinical trial, could materially harm our business, financial condition and results of operations.

We or our licensees may experience delays or difficulties in the enrollment and/or retention of patients in clinical trials, which could delay or prevent our receipt of necessary regulatory approvals.

Successful and timely completion of clinical trials will require that we or our licensees sponsoring trials for our product candidates enroll a sufficient number of subjects. Subject enrollment, which is an important factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population and competition for patients eligible for our clinical trials with competitors which may have ongoing clinical trials for product candidates that are under development to treat the same indications as one or more of our product candidates, or approved products for the conditions for which we are developing our product candidates.

Trials may be subject to delays as a result of subject enrollment taking longer than anticipated or subject withdrawal. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities. We cannot predict how successful we or our licensees will be at enrolling subjects in future clinical trials. Subject enrollment is affected by other factors including:

- the severity and difficulty of diagnosing the disease under investigation;
- the eligibility and exclusion criteria for the trial in question;
- the size of the patient population and process for identifying patients;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the design of the trial protocol;
- the perceived risks and benefits of the product candidate in the trial in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- the availability of competing commercially available therapies and other competing therapeutic candidates' clinical trials for the disease or condition under investigation;
- the willingness of patients to be enrolled in our clinical trials;
- the risk that subjects enrolled in clinical trials will drop out of our trials before completion;
- our ability to obtain and maintain clinical trial subject informed consents
- the efforts to facilitate timely enrollment in clinical trials;

- potential disruptions caused by geopolitical events such as the Russian invasion of Ukraine;
- the patient referral practices of physicians;
- the ability to monitor subjects adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective subjects.

Inability to enroll a sufficient number of subjects for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in these clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Furthermore, we rely on contract research organizations (CROs) and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we have limited influence over their performance.

Interim "top-line" and preliminary results from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim top-line or preliminary results from our clinical trials. Interim results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully evaluate all data. Preliminary or top-line results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated, and should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could be material and could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

Furthermore, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or therapeutic product, if any, and us in general. The information we choose to publicly disclose regarding a particular nonclinical study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular therapeutic product, if any, product candidate or our business. If the preliminary, interim and topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

The FDA or comparable foreign regulatory authorities may disagree with our regulatory plans and we may fail to obtain regulatory approval of our product candidates.

Our clinical trial results may not support regulatory approval of our product candidates. The results of nonclinical studies and clinical trials may not be predictive of the results of later-stage clinical trials, and product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and initial clinical trials. In addition, our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- we may be unable to demonstrate that our product candidates' risk-benefit ratios for their proposed indications are acceptable;

- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;

- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;

- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of an application for marketing authorization to FDA or comparable foreign regulatory authorities;

- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, our own manufacturing facilities, or a third-party manufacturer's facilities with which we contract for clinical and commercial supplies; and

- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Failure to obtain regulatory approval to market any of our product candidates would significantly harm our business, results of operations, and prospects.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval and limit the commercial profile of an approved label, and such side effects or other properties could result in significant negative consequences following any marketing approval of any of our product candidates.

Undesirable side effects caused by any of our product candidates could cause us, our licensing partners, if any, or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority. Results of the clinical trials could reveal a high and unacceptable severity and prevalence of side effects or risks associated with a product candidate's use. In such an event, our trials could be suspended or terminated and the regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if undesirable side effects of our products are identified following marketing approval, 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 subjects or 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 product candidates could delay or prevent regulatory approval of our product candidates, limit the commercial profile of an approved label for our product candidates, or result in significant negative consequences for our product candidates following marketing approval.

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

We might not be able to develop marketable products utilizing our technology and we might not be able to identify and successfully implement an alternative product development strategy.

The approach we have adopted to discover and develop product candidates is new and may never lead to marketable products. We have concentrated our efforts on developing therapeutic product candidates utilizing new advanced technology for drug delivery. To our knowledge, no person or company has developed any therapeutic product utilizing the same technology and no such ophthalmic micro-therapeutic product has been approved for marketing to date. We are leading a new field of ophthalmic micro-therapeutic research and development and the scientific discoveries that form the basis for our efforts to develop products are relatively new. The scientific evidence to support the feasibility of developing such products and treatments based on these discoveries is limited. Our focus solely on developing products utilizing our proprietary technology, as opposed to more traditional technology, increases the risks associated with investing in our stock. If we are unsuccessful in developing product candidates utilizing our technology or finding additional applications for our technology, we may be required to change the scope and direction of our product development activities. If we are not able to identify and successfully implement an alternative product development strategy, our business may fail.

If the market opportunities for our product candidates 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 our Mydcombi product candidate, and we have licensed commercialization rights to Mydcombi as well as MicroPine and MicroLine 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) and to MicroPine in the United States and Canada to Bausch Health. 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 candidates 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, progressive myopia and presbyopia. 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 product candidates 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 our product candidates 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.

Even if we receive regulatory approval to market our product candidates, our product candidates might not gain market acceptance upon their commercial introduction, which could prevent us from becoming profitable.

We may have difficulties convincing the medical community, third-party payors and consumers to accept and use any of our product candidates that may be approved for commercialization in the future. Other factors that we believe will affect market acceptance of our product candidates 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 our product candidates;
- the success of physician education programs;
- the availability of any government and third-party payor reimbursement;
- the pricing of our product candidates, 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 any product candidates that we may develop in the future; and

- the prevalence and severity of any adverse effects.

Our licensing partners may fail to use commercially reasonable efforts to commercialize certain of our products.

Our licensing partners are contractually obligated to use commercially reasonable efforts in the commercialization of the products for which they have negotiated a license. Uncovering that one or more of our partners is not using commercially reasonable efforts could take time to discover and time to remedy, during which the sales of our products candidates could be lower than we expect.

We face competition in an environment of rapid technological change and the possibility that our competitors may achieve regulatory approval before us or 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 product candidates.

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 current or any future therapeutic 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 any therapeutic products that we may develop. 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 the product candidates for which we obtain marketing approval, we will need to establish and maintain an adequate sales force, and additional manufacturing, marketing and distribution capabilities, either ourselves or through collaborations or other arrangements with third parties. In addition, failure to secure contracts with manufacturers, wholesalers, retailers, or specialty pharmacies could negatively impact the production and distribution of our potential 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 launch and sales of our potential products may be delayed or 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 clinical trials or for loss or harm suffered by users of any drug that may receive approval for commercialization in the future. 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 clinical trial or commercialized drug, the manufacturing processes and facilities or marketing programs utilized in respect of any such clinical trial or drug. Such investigations may result in mandatory or voluntary recalls of any 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. Investigations by the FDA or any other regulatory authority in other countries or regions also could delay or prevent the completion of any of our other clinical development programs.

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 our product candidates that we develop in human clinical trials. We face an even greater risk if we commercially sell any products that we develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to clinical trial participants or patients;
- loss of revenue;
- reduced time and attention of our management to pursue our business strategy; and
- the inability to commercialize any products that we develop.

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 expand or undertake new our clinical trials for existing and future product candidates. We will need to further increase our insurance coverage if we commence commercialization of any of the product candidates for which we obtain marketing approval. 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 our product candidates, if approved, due to unfavorable pricing regulations or third-party coverage and reimbursement policies, which could make it difficult for us to sell our product candidates 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 newly approved 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. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. 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.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. 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 any product that we commercialize 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 any approved products that we develop 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, any product for which we obtain marketing approval. 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 new product's acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new 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 (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 any of our product candidates 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 any approved product.

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 product candidates may lose any regulatory approval that may have 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 PRODUCT CANDIDATES AND OTHER LEGAL COMPLIANCE MATTERS

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable. If we are not able to obtain required regulatory approval for any of our current or future product candidates, our business may be materially and adversely affected.

The time required to obtain approval or other marketing authorizations by the FDA and comparable foreign authorities is unpredictable, and it typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, and the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate, and it is possible that we may never obtain regulatory approval for any product candidates we may seek to develop in the future. Neither we nor any current or future collaborator is permitted to market any drug or drug-led combination product candidate in the United States until FDA approval of an NDA is obtained, and we cannot market such a product candidate in any other country until we obtain regulatory authorization as required under the laws of such country.

Prior to obtaining approval to commercialize any biologic product candidate in the United States or abroad, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or other foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from nonclinical or preclinical studies and clinical trials may be interpreted differently by different regulatory agencies. Even if we believe the nonclinical or clinical data for Mydcombi, MicroPine, and MicroLine are promising, such data may be insufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional nonclinical studies or clinical trials for our products either prior to or after approval, or it may object to elements of our clinical development programs. This could result in substantial additional costs or delays in the development of our product candidates.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of our clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may fail to approve our manufacturing processes or facilities of third-party suppliers with which we contract for clinical and commercial supplies of our product candidates; and
- the approval policies or regulations of the FDA or comparable foreign authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of product candidates developed by pharmaceutical manufacturers, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval and marketing authorization process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval and marketing authorization to market Mydcombi, MicroPine, MicroLine, or any of our future product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

We have invested a significant portion of our time and financial resources in the development of our product candidates. Our business is dependent on our ability to successfully complete nonclinical and clinical development of, obtain regulatory approval for, and, if approved, successfully commercialize such product candidates in a timely manner.

Even if we receive approval of an NDA or foreign marketing application for Mydcombi, MicroPine, MicroLine or any future product candidates, the FDA or the applicable foreign regulatory agency may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-marketing clinical trials. The FDA or the applicable foreign regulatory agency also may approve or authorize for marketing a product candidate for a more limited indication or patient population than we originally request or may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval or other marketing authorization would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

In addition, the FDA and other regulatory authorities may change their policies, issue additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval of our future product candidates on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

We submitted an NDA to the FDA for marketing approval of Mydcombi for mydriasis to facilitate the over 100 million estimated office-based comprehensive and diabetic eye exams and four million ophthalmic surgical dilations performed every year in the United States. In October 2021, we received a CRL from the FDA, which in part informed us that pre-filled or co-packaged ophthalmic drug dispenser products like Mydcombi have been reclassified as drug-device combination products. As a result, we resubmitted the NDA for Mydcombi providing additional non-clinical device information, and the FDA accepted the resubmitted NDA for filing and review in December 2022, with a PDUFA date of May 8, 2023. However, even if we addressed all of the issues identified in the CRL, the FDA may ultimately decide that the application does not satisfy the applicable regulatory criteria and may decline to approve Mydcombi for commercialization, which would materially adversely impact our business.

Mydcombi is a drug/device combination and the process for obtaining regulatory approval in the United States will require compliance with complex procedures because concordance between two centers of the FDA (CDRH and CDER) is necessary for approval of this combination product. A change in the FDA's prior determination that CDER would lead the review of a marketing application for Mydcombi would adversely impact its development timeline and significantly raise our costs to complete clinical development and obtain regulatory approval for Mydcombi.

Mydcombi is a drug product for mydriasis that is intended to be administered to a patient via our Optejet dispenser, which uses our microdose array print, or MAP, technology. In October 2021, we received a CRL from the FDA, which in part informed us that pre-filled or co-packaged ophthalmic drug dispenser products like Mydcombi have been reclassified as drug-device combination products. If the designation were to be changed, or if either CDER or CDRH were to institute additional requirements for the approval of Mydcombi, we could be required to complete clinical studies with more patients and over longer periods of time than is currently anticipated. This would significantly increase the anticipated cost and timeline to completion of Mydcombi's development and require us to raise additional funds. The FDA may determine that the results of our completed clinical trials are not sufficiently robust or convincing and require additional clinical and/or nonclinical studies prior to approval of Mydcombi. Because Mydcombi is our lead product candidate, the impact of either a change in the lead FDA review center or the imposition of additional, currently unanticipated requirements for approval could be significant to us and have a material adverse effect on the prospects for developing Mydcombi, as well as on our business and our financial condition.

Furthermore, we anticipate that our other product candidates in development, MicroPine and MicroLine, will also be considered drug/device combination products because, like Mydcombi, they are also pre-filled or co-packaged ophthalmic drug dispenser products intended for use only with the Optejet dispenser.

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

If the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, storage, advertising, promotion, import, export, recordkeeping, monitoring, and reporting of our product will be 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. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing studies, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of the product.

The FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. 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;
- suspension of any of our ongoing clinical trials;
- 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 develop and 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 regulatory approval of our product candidates. 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.

Even if we obtain FDA approval for any of our product candidates in the United States, we may never obtain approval for or commercialize any of them 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. 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 any product candidates for which we obtain marketing approval. 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 candidate, the regulatory approval is limited to those specific uses and indications for which a product is approved. If we are not able to obtain FDA or comparable foreign regulatory authority approval for desired uses or indications for our current product candidates and any future product candidates, 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 any of our current product candidates and any future product candidates, 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 our products, following approval, 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, if any, 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 after one or more of our current or future product candidates obtains marketing approval 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 will be subject to applicable anti-kickback, fraud and abuse and other health care laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Although we do not currently have any products on the market, upon commercialization of Mydcombi, MicroPine, MicroLine, or any of our future product candidates, if approved, we will be subject to additional 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, or the AKS, and the FCA, 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 AKS; 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, or 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 (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.

Most 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 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, or 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, 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 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, or FCPA, and the United Kingdom Bribery Act 2010, or 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., U.S. 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 attract, retain and motivate highly qualified additional management, clinical, scientific, and sales personnel. If we are not able to retain our management and to attract, on acceptable terms, additional qualified personnel necessary for the continued development of our business and commercialization of our product candidates, we might not be able to sustain our operations or grow.

We might not be able to attract or 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 attract, retain and motivate high-quality personnel and consultants to accomplish our business objectives, the rate and success at which we can discover and develop drug candidates and our business will be limited and we may experience constraints on our development objectives.

Our future performance will also depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management.

We have limited corporate infrastructure and may experience difficulties in managing growth.

As of March 30, 2023, we had only 41 full time employees and we rely on third-party contractors for the provision of professional and other services. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial, legal and other resources. 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 these growth activities. We might not be able to effectively manage the expansion of our 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 expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our current and potential future drug candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and grow revenue could be reduced and we might not be able to implement our business strategy. Our future financial performance, our ability to commercialize drug candidates, develop a scalable infrastructure and compete effectively will depend, in part, on our ability to effectively manage any future growth.

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.

Our business operations could suffer in the event of system failure. Despite the implementation of security measures, our internal computer systems and those of our contract research organizations, and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. 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 liability and further development of our product candidates could be delayed.

Our employees, principal investigators, 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, principal investigators, 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 rely on third parties to conduct, supervise, and monitor our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. As a result, we are and expect to remain dependent on third parties to conduct our current and future preclinical studies and clinical trials. CROs that manage our preclinical studies and clinical trials as well as clinical investigators, including in investigator-initiated clinical trials, and consultants play a significant role in the conduct of our preclinical studies and clinical trials and the subsequent collection and analysis of data. The timing of the initiation and completion of these studies and trials will therefore be partially controlled by such third parties and may result in delays to our development programs. Nevertheless, we are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal requirements, and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GLP and GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities

for all of our product candidates in clinical development. Regulatory authorities enforce these GLP and GCP requirements through periodic inspections of preclinical study sites, trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs or clinical trial sites, including clinical trial sites in investigator-initiated clinical trials, fail to comply with applicable GLP or GCP requirements, the data generated in our preclinical studies and clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional preclinical or clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to stop and/or repeat clinical trials, which would delay the marketing approval process. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, clinicaltrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. If any of these third parties fails to meet expected deadlines, adhere to our clinical protocols or comply with applicable regulatory requirements, otherwise performs in a substandard manner, or terminates its engagement with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If any of our clinical trial sites terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trials unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible. In addition, clinical trial investigators for our clinical trials or investigator-initiated clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or any comparable foreign regulatory authority concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any marketing application we submit by the FDA or any comparable foreign regulatory authority. Any such delay or rejection could prevent us from commercializing our product candidates.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, or at all. Further, under certain circumstances, these third parties may terminate their agreements with us upon prior written notice. Entering into arrangements with alternative CROs, clinical trial investigators or other third parties involves additional cost and requires management focus and time, in addition to requiring a transition period when a new CRO, clinical trial investigator or other third party begins work. If third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain are compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such third parties are associated with may be extended, delayed or terminated, and we may not be able to obtain marketing approval for or successfully commercialize our product candidates. As a result, we believe that our financial results and the commercial prospects for our product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Furthermore, any CROs we contract with or clinical investigators that conduct investigator-initiated studies involving our product candidates may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct the clinical trials in accordance with regulatory requirements or the corresponding protocols, as applicable, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our products.

We are contracting with third parties for the manufacture of components of our product candidates, particularly for commercialization, just as we do to provide materials required for the production of the Optejet and for some of our current research and development activities. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development and 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 clinical or commercial production of our product candidates. In addition, we rely on, and expect to continue to rely on, a number of third parties for the supply of parts, formulations, active pharmaceutical ingredients, and other materials required for our research and development activities. If we are unable to establish adequate manufacturing processes internally or to reach and maintain agreements with third parties to help us, our research and development, manufacturing, and commercialization activities would be delayed.

We rely on third parties to provide the materials required for our research and development activities. Reliance on third-party providers may expose us to more risk than if we were to manufacture our product candidates 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 product candidates 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 our product candidates. 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 research and development 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 product candidates and may need to rely on them extensively for adequate supply of our products during commercialization. If we were unable to acquire the necessary amount of deliverables to complete our clinical trials and ultimately commercialize our products, our progress 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 our product candidates in the quantities needed for our clinical trials or, if our product candidates are approved, in sufficient quantities for commercialization or to meet an increase in demand, 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 our product candidates, may have a material adverse effect on our business.

Our third-party suppliers may be subject to inspection and approval by regulatory authorities before we can commence the manufacture and sale of any of our product candidates, and thereafter are subject to ongoing inspection from time to time. 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 product candidates or drugs, 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 our product candidates 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 product candidates and any products that may obtain approval in the future. Any such changes could require the conduct of bridging studies before we can use any materials produced at new facilities or under new processes in clinical trials or, for any products reaching approval, 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. For these reasons, a significant disruptive event of any third-party suppliers could have drastic consequences, including placing our financial stability at risk.

Our product candidates and any drugs that we may develop 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 any of our product candidates, we could experience delays in our planned clinical studies or commercialization. For example, the COVID-19 pandemic may impact our ability to procure sufficient supplies for the development of our current and future product candidates, and the extent of such impacts will depend on the severity and duration of the spread of the virus and the actions undertaken to contain COVID-19 or treat its effects. 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 our clinical trials and, for any product candidates that reach approval, the commercialization of our products, 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 research and development activities, and the research and development activities of our service providers and third-party manufacturers, 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 product candidates successfully and could harm our reputation and lead to reduced acceptance of our product candidates. These enforcement actions may include:

- restrictions on, or prohibitions against, marketing our product candidates;
- restrictions on importation of our product candidates;
- suspension of review or refusal to approve new or pending applications;
- 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 product candidates. 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. To protect our proprietary position, we file patent applications in the United States and abroad related to our novel product candidates that are important to our business. 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 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 scientists and 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 product candidates 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 product candidates 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 potential product candidates;

- 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 product candidates.

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 and product candidates, 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 and product candidates 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 product candidates 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.

In addition, to the extent that we are unable to obtain and maintain patent protection for one of our products or product candidates or in the event that such patent protection expires, it may no longer be cost-effective to extend our portfolio by pursuing additional development of a product or product candidate for follow-on indications. 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 each of our product candidates, 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. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. 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 product candidates.

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. 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 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. However, we might not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced and could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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 product candidates 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 developing or commercializing our product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our product candidates 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 for which we are developing our product candidates that may cover our product candidates or approach to complement inhibition. If any third-party patents or patent applications are found to cover our product candidates or their methods of use or manufacture, or our approach to complement inhibition, we might not be free to manufacture or market our product candidates 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 product candidates, 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 product candidates. 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 product candidates 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 product candidates 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 product candidates, 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 and scientific personnel 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 developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate or 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 product candidates 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 senior management and scientific personnel. 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 development 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 develop or 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 develop and commercialize the affected product candidates, 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 development 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 develop and commercialize the product candidates 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 develop or commercialize the affected product candidates, 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 28, 2023, we had 37,991,746 shares of common stock outstanding, 1,125,831 shares of common stock issuable upon exercise of warrants issued in the private placement completed in March 2020, which may be resold without restriction, and 4,870,130 shares of our common stock issuable upon exercise of warrants and pre-funded warrants issued in the registered direct offering completed in March 2022.

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 2022. 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 our IPO in

January 2018 through March 30, 2023, the per share trading price of our common stock has been as high as $10.74 and as low as $1.50. It 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 evolving coronavirus pandemic and geopolitical events such as the Russian invasion of Ukraine;
- our ability to successfully conduct clinical trials, submit NDAs and gain marketing approval for our product candidates;
- results of clinical trials of our product candidates or those of our competitors;
- 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;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates;
- 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;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- 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;
- 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.

Our business is subject to changing regulations regarding corporate governance, disclosure controls, internal control over financial reporting, and other compliance areas that will increase both our costs and the risk of noncompliance.

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.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. Commencing with our fiscal year ending December 31, 2018, we performed system and process evaluation and testing of our internal control over financial reporting so that management could report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our compliance with Section 404 of the Sarbanes-Oxley Act requires that we incur substantial accounting expense and expend significant management efforts. Prior to our IPO, we had never been required to test our internal controls within a specified period.

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.

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. Inflation can adversely affect us by increasing the costs of clinical trials and research, the development of our product candidates, administration and other costs of doing business. 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.

Failure to develop and maintain adequate financial controls could cause us to have material weaknesses, which could adversely affect our operations and financial position.

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 "emerging growth company" and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an emerging growth company. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards.

For as long as we continue to be an emerging growth company, we intend to take advantage of certain other exemptions from various reporting requirements that are applicable to other public companies including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved, and exemptions from the requirements of auditor attestation reports on the effectiveness of our internal control over financial reporting. We cannot predict if investors will find our common stock less attractive because we will 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 stock price may be more volatile.

We will remain an emerging growth company until the earliest of (i) the end of the fiscal year in which the market value of our common stock that is held by non-affiliates exceeds $700 million as of June 30 of that fiscal year, (ii) the end of the fiscal year in which we have total annual gross revenue of $1.07 billion or more during such fiscal year, (iii) the date on which we issue more than $1 billion in non-convertible debt in a three-year period, or (iv) December 31, 2023.

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.

Item 1B. Unresolved Staff Comments.

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

Item 2. Properties.

Our principal executive offices are located in approximately 3,800 square feet of office space in New York City, NY. In addition, we lease approximately 12,000 square feet of office space in Reno, Nevada where we perform certain of our research and development activities. We also lease approximately 6,700 square feet for a planned commercial manufacturing facility in Redwood City, California and 4,600 square feet of office space in Laguna Hills, California for clinical, medical affairs and the commercial team offices.

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 28, 2023, we had approximately 37 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, 2022 and 2021, 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 a pre-commercial ophthalmic technology company developing the Optejet® delivery system for use both in combination with our own drug-device therapeutic programs as well as out-licensing for additional indications. Our aim is to improve the delivery of topical ophthalmic medication through ergonomic design that facilitates ease-of-use, delivery of more physiologically appropriate medication volume, with the goal to reduce side effects and improve tolerability, and introduce digital health technology to improve therapy compliance and ultimately medical outcomes.

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 faster than the blink reflex to help ensure instillation success. The precise delivery of a low-volume columnar spray by the Optejet® device minimizes contamination 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 ~ 50%.

A more physiologically appropriate volume of medication in the range of seven to nine microliters is delivered by the Optejet, 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.

Versions of the Optejet are being developed with on-board digital technology to provide reminders via Bluetooth to smart devices and date and time stamp device use. 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.

Our drug-device therapeutic programs include MicroPine, MicroLine and Mydcombi™. MicroPine is our first-in-class topical therapy for the treatment of progressive myopia, a back-of-the-eye ocular disease associated with pathologic axial elongation and sclero-retinal stretching. In the United States, myopia is estimated to affect approximately 25 million children, with up to five million considered to be at high risk for progressive myopia. In February 2019, the FDA accepted our IND to initiate the CHAPERONE study to reduce the progression of myopia in children. The first patient was enrolled in the CHAPERONE study in June 2019.

On October 9, 2020, we entered into the Bausch License Agreement with Bausch + Lomb, pursuant to which Bausch + Lomb may 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 may receive up to a total of $35.0 million in additional payments, based on the achievement of certain regulatory and launch-based milestones. Bausch + Lomb also will 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, Bausch + Lomb assumed sponsorship of the IND as well as ownership and the costs related to the ongoing CHAPERONE study.

We have also successfully expanded our manufacturing capabilities through a partnership with Coastline International, Inc. located in Tijuana, Mexico, and the construction of our own fill and finish facility in Redwood City, California. As of the date of filing, we are up-to-date supplying clinical product for this study.

MicroLine is our investigational pharmacologic treatment for presbyopia. Presbyopia is 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. Allergan recently launched Vuity™, a pilocarpine drug product for the treatment of presbyopia. Our second Phase III study, VISION-2, used the same drug, delivered with the advantages of our Optejet® device. We released positive top-line results from VISION-2 in the fourth quarter of 2022.

Mydcombi™ is our fixed combination formulation of tropicamide-phenylephrine for mydriasis and a novel approach for the over 100 million office-based comprehensive and diabetic eye exams performed every year in the United States. We completed two Phase III trials for Mydcombi and announced positive results from these studies, known as MIST-1 and MIST-2, and have submitted an NDA to the FDA seeking approval to market the product in the U.S. In October 2021, we received a CRL in response to our NDA, which in part informed us that pre-filled or co-packaged ophthalmic drug dispenser products like Mydcombi had been reclassified as drug-device combination products. This reclassification was based upon the U.S. Court of Appeals for the D.C. Circuit's decision in Genus Medical Technologies v. FDA, not involving Eyenovia, which ordered that products meeting the statutory definition of a device but were previously classified by the FDA as drugs must be regulated as devices. Before this ruling, the FDA regulated pre-filled or co-packaged ophthalmic dispensers as part of the approved ophthalmic drug distributed and sold with the dispenser. After the ruling, however, the dispenser must be considered as a distinct device constituent part of a drug-device combination product. We resubmitted the NDA on November 8, 2022, and announced on December 13, 2022 that the FDA has accepted the resubmission. The FDA has assigned the resubmitted NDA a standard review with a Prescription Drug User Fee Act (PDUFA) target action date of May 8, 2023.

On August 10, 2020, we entered into the Arctic Vision License Agreement with Arctic Vision, which was amended on September 14, 2021, pursuant to which Arctic Vision may develop and commercialize MicroPine, 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. In addition, we may receive up to a total of $39.7 million in additional payments, based on various development and regulatory milestones, including the initiation of clinical research and approvals in Greater China and South Korea, and development costs. Arctic Vision also will purchase its supply of MicroPine, MicroLine and Mydcombi from Eyenovia or, for such products not supplied by Eyenovia, pay a mid-single digit percentage royalty on net sales of such products, subject to certain adjustments. We will pay between 30 and 40 percent of such payments, royalties, or net proceeds of such supply to Senju pursuant to an exclusive license agreement with Senju dated March 8, 2015, as amended. See Note 2— Summary of Significant Accounting Policies—Arctic Vision License Agreement and Note 10—Related Party Transactions —Senju License Agreement to our audited financial statements included in this Annual Report on Form 10-K for further details.

We are in active discussions with manufacturers of existing and late-stage ophthalmic medications to explore whether development with the Optejet technology can solve unmet medical and business needs. Some of those business needs could include extension of exclusivity under the Optejet patents, improvement in a drug's tolerability profile, or potential improvement in treatment compliance.

Historically, we have financed our operations principally through equity offerings. We have also generated cash through licensing arrangements and our credit facilities with SVB and 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 these financial statements are issued. Our ability to continue as a going concern depends on our ability to complete additional licensing or business development transactions or raise additional capital, through the sale of equity or debt securities to support our future operations. If we are unable to secure additional capital, we may be required to curtail our research and development initiatives and take additional measures to reduce costs.

Our net losses were $28.0 million and $12.8 million for the years ended December 31, 2022 and 2021. As of December 31, 2022, we had working capital and an accumulated deficit of approximately $23.1 million and $118.2 million, respectively.

Financial Overview

Revenue and Cost of Revenue

In August and October 2020, we entered into the Arctic Vision License Agreement and Bausch License Agreement, respectively. Both of these agreements provide for the Company to earn revenue from an upfront licensing fee, the achievement of various development and regulatory milestones, and royalty income on sales of licensed products. Pursuant to the Senju License

agreement, we will pay a percentage between 30 and 40 percent of such payments from the Arctic Vision License Agreement to Senju. See Note 10 – Related Party Transactions in the accompanying financial statements for the years ended December 31, 2022 and 2021.

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 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.

We expect that our research and development expenses will increase with the continuation of the aforementioned initiatives.

General and Administrative Expenses

General and administrative expenses consist primarily of payroll and related expenses, legal and other professional services, insurance expense, and non-cash stock-based compensation expense. We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development and the potential commercialization of our product candidates.

Results of Operations

Year Ended December 31, 2022 Compared with Year Ended December 31, 2021

Revenue and Cost of Revenue

In August 2020, we received a non-refundable, upfront payment of $4.0 million under the terms of the Arctic Vision License Agreement, which was recorded as deferred license fees until such time that the related performance obligation was satisfied and the payment was earned. Payment is earned and revenue is recognized once certain trial data has been fully submitted to Arctic Vision, permitting Arctic Vision to seek regulatory approval with the National Medical Products Administration of China. The trial data for one of the two products (MicroPine) was fully submitted to Arctic Vision in March 2021 and trial data for the other product (MicroLine) was fully submitted to Arctic Vision in June 2021. As a result, we recognized the deferred license fees as revenue during the year ended December 31, 2021. Pursuant to the terms of the Senju License Agreement, we are required to pay Senju a percentage of payments received from Arctic Vision. Accordingly, we accrued $1.6 million of license costs related to payments to Senju in connection with the upfront license fees received from Arctic Vision, which is reflected as cost of revenue for the year ended December 31, 2021 (see Note 10 – Related Party Transactions in the accompanying financial statements for the years ended December 31, 2022 and 2021). On September 14, 2021, we executed Amendment 1 to the Arctic Vision License Agreement, which provides for a one-time upfront payment to us of $250,000 and milestone payments to us of $2.0 million based on the achievement of certain milestones. We did not recognize revenue for the $250,000 upfront payment because it was passed through to Senju pursuant to our agreement with them.

In October 2020, we received a $10.0 million upfront payment under the Bausch Health License Agreement. We recorded this payment as a deferred license fee until certain trial data was fully submitted to Bausch Health and clinical trial supervisory oversight

was transferred to Bausch Health. The required trial data and oversight functions were transferred to Bausch Health during the fourth quarter of 2021. Accordingly, the upfront payment was earned and recognized as revenue during the year ended December 31, 2021.

No revenue was earned or recognized during the year ended December 31, 2022.

Research and Development Expenses

Research and development expenses for the year ended December 31, 2022 totaled $13.4 million, a decrease of $1.5 million, or 10%, as compared to $14.9 million recorded for the year ended December 31, 2021. Research and development expenses consisted of the following:

	For the Year Ended December 31,	
	2022	2021
Personnel-related expenses	$ 6,070,577	$ 5,393,241
Supplies and materials	2,731,743	1,271,234
Non-cash stock-based compensation expenses	1,809,305	1,612,942
Direct clinical and non-clinical expenses	1,005,661	5,045,518
Facilities expenses	994,069	1,153,337
Other expenses	767,325	374,602
Total research and development expenses	$ 13,378,680	$ 14,850,874

The increase in personnel-related expenses and non-cash stock-based compensation expenses was primarily due to new hires. The increase in supplies and materials was primarily due to costs expended for clinical dispenser cartridge supplies in 2022. The decrease in direct clinical and non-clinical expenses resulted from the sharp decrease in expenses resulting from Bausch + Lomb assuming full control of its clinical trial in December 2021 and the Vision 2 study in 2022 costing less than the Vision 1 study completed in 2021. The increase in other expense primarily reflects additional travel expenses due to the easing of COVID-19 restrictions.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2022 totaled $13.5 million, an increase of $2.9 million, or 27%, as compared to $10.6 million recorded for the year ended December 31, 2021. General and administrative expenses consisted of the following:

	For the Year Ended December 31,	
	2022	2021
Salaries and benefits	$ 3,842,993	$ 2,875,884
Professional fees	3,427,450	1,963,233
Stock-based compensation	1,956,059	1,273,160
Other	1,260,732	1,151,678
Sales and marketing	1,203,767	1,964,192
Insurance expense	1,061,505	917,548
Director fees and expense	398,125	318,250
Facilities expense	382,204	105,707
	$ 13,532,835	$ 10,569,652

The increase in salaries and benefits and stock-based compensation was primarily attributable to new hires as we ramp up for the commercialization stage. The increase in professional fees was primarily due to higher legal and professional recruiting expenses related to the addition of new directors in 2022. The decrease in sales and marketing primarily related to the Mydcombi promotional campaign and trade show expenses incurred for the anticipated launch in late 2021. The timing of that launch has been delayed.

Other Income (Expense)

Other income (expense) for the year ended December 31, 2022 totaled approximately $1.1 million of net other expense, a change of approximately $1.3 million, as compared to $0.2 million of net other income for the year ended December 31, 2021. Net other expense for the year ended December 31, 2022 primarily consisted of approximately $1.4 million of interest expense related to the SVB loan payoff and the Avenue loan, primarily offset by $0.2 million of income from the sale of clinical supplies and $0.1 million of interest income. Net other income for the year ended December 31, 2021 primarily consisted of an approximately $0.5 million gain on extinguishment of the PPP (7a) loan, primarily offset by approximately $0.4 million of interest expense primarily related to a loan we entered into with SVB in 2021.

Liquidity and Going Concern

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

	December 31,	
	2022	2021
Cash and Cash Equivalents	$ 22,863,520	$ 19,461,850
Restricted Cash	—	7,875,000
Total	$ 22,863,520	$ 27,336,850
Working Capital	$ 23,130,178	$ 10,829,363
Notes Payable (Gross)	$ 10,425,000	$ 7,500,000

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, 2022, our accumulated deficit since inception was approximately $118.2 million.

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 and competing market developments.During the years ended December 31, 2022 and 2021, our sources and uses of cash were as follows:

Net cash used in operating activities for the year ended December 31, 2022 was approximately $25.1 million, which includes cash used to fund a net loss of $28.0 million, reduced by $2.3 million of net cash used by changes in the levels of operating assets and liabilities, offset by $5.2 million of non-cash expenses. Net cash used in operating activities for the year ended December 31, 2021 was approximately $20.9 million, which includes cash used to fund a net loss of $12.8 million, reduced by $10.7 million of net cash used by changes in the levels of operating assets and liabilities, offset by $2.6 million of net non-cash expenses.

Net cash used in investing activities was approximately $0.9 million and $1.6 million for the years ended December 31, 2022 and 2021, respectively, which was attributable to purchases of property and equipment.

Net cash provided by financing activities for the year ended December 31, 2022 totaled approximately $21.5 million, which was primarily attributable to $14.9 million of net proceeds from the sale of common stock and warrants from a registered direct offering, $5.3 million of net proceeds from the sale of common stock and warrants in our at-the-market offering pursuant to the Sales Agreement with SVB Securities LLC, or SVB Securities (formerly known as SVB Leerink LLC), and $9.5 million of net proceeds from the credit facility with Avenue, offset by $8.2 million from the repayment of notes payable. Net cash provided by financing activities for the year ended December 31, 2021 totaled approximately $21.5 million, which was primarily attributable to $12.4 million of net proceeds from the sale of common stock and warrants in our at-the-market offering pursuant to the Sales Agreement, dated May 14, 2021, with SVB Securities, $2.1 million of proceeds from exercises of stock warrants, $7.4 million of net proceeds from the credit facility with SVB Securities, $0.2 million of proceeds from the exercise of stock options, offset by $0.7 million from the repayments of notes payable.

Contractual Obligations and Commitments

During the next twelve months we have commitments to pay (a) $3.7 million to settle our December 31, 2022 accounts payable, accrued expenses and other current liabilities, (b) $0.5 million relating to our non-cancelable operating lease commitments; (c) $1.0 million of potential executive severance pay; and (d) $0.4 million of gross payments due under our notes payable and convertible notes payable (if not previously converted).

After twelve months we have commitments to pay (a) an additional $0.9 million relating to our non-cancelable operating lease commitments, and $10.0 million of gross payments due in connection with notes payable and convertible notes payable (if not previously converted).

Avenue Loan Agreement

On November 22, 2022, we entered into a Loan and Security Agreement, or the Avenue Loan with Avenue Venture Opportunities Fund, L.P., or Avenue 1 and Avenue Venture Opportunities Fund, L.P. II, or Avenue 2, for an aggregate principal amount of up to $15,000,000. The initial tranche of the Avenue Loan is $10,000,000, consisting of $4,000,000 from Avenue 1 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 $2.148 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. We may request an additional $5,000,000 of gross funding between April 1, 2023 and July 31, 2023, subject to agreed-upon conditions. We must also make an incremental final payment equal to 4.25% of the aggregate funding.

We are required to 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, we will make equal monthly payments of principal until the maturity date, plus interest. If we prepay the Avenue Loan, we 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.

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, 2022, we had unrestricted cash and cash equivalents of approximately $22.9 million and an accumulated deficit of approximately $118.2 million. For the years ended December 31, 2022 and 2021, we incurred net losses of approximately $28.0 million and $12.8 million, respectively, and used cash in operations of approximately $25.1 million and $20.9 million, respectively. We do not have recurring revenue and have not yet achieved profitability. We expect to continue to incur cash outflows from operations. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will eventually need to generate significant product revenues to achieve profitability. 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 or our ability to raise further capital, through the sale of additional equity or debt securities 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 or secure additional capital, we may be required to curtail our research and development initiatives and take additional measures to reduce costs in order to conserve our cash.

Risks and Uncertainties

As of March 15, 2023, the amount of our assets held on deposit with SVB is immaterial with respect to our total cash, cash equivalents and marketable securities. We do not expect that SVB's liquidity concern will have a significant adverse impact on our operations due to our limited exposure to SVB and the Federal Reserve's decision to make all of SVB's depositors whole. We will continue to monitor the situation with SVB as it evolves.

The continuing worldwide implications of the war between Russia and Ukraine 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 Policies

The following represent our most critical accounting policies:

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. We base our 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 our 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 recovery of deferred costs and the deferral of revenues. Certain of our estimates could be affected by external conditions, including those unique to us and general economic conditions. It is reasonably possible that actual results could differ from those estimates.

Impairment of Long-lived Assets

We review 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.

Revenue Recognition

Our revenues are generated primarily through research, development and commercialization agreements. The terms of such agreements may contain multiple promised goods and services, which may include (i) licenses to our intellectual property, and (ii) in certain cases, payment in connection with the manufacturing and delivery of clinical supply materials. Payments to us 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.

We analyze our 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, we allocate 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. Our policy is to recognize amounts allocated to joint operating activities as a reduction in research and development expense.

Under ASC 606, we recognize revenue when our customers obtain control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform 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.

We must make significant judgments in our 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. In addition, arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered discretionary purchase options. We assess if these options provide a material right to the customer and if so, they are considered performance obligations.

For upfront license fees, we must consider how many performance obligations are in the contract and, if more than one, how to allocate the fee to those performance obligations upon satisfaction of the performance obligation(s). 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.

Stock-Based Compensation

We measure 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.

Operating Leases

We adopted the Accounting Standards Update, or ASU 2016-02,"Leases (Topic 842)" as of December 31, 2022, effective January 1, 2022. We lease our facilities under non-cancellable operating leases. We evaluate the nature of each lease at the inception of an arrangement to determine whether it is an operating or financing lease and recognizes the ROU asset and lease liabilities based on the present value of future minimum lease payments over the expected lease term. We recognize 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 our incremental borrowing rate. Our leases do not generally contain an implicit interest rate and therefore the we use 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.

Recently Issued Accounting Standards

Our recently issued accounting standards are included in Note 2 – Summary of Significant Accounting Policies of our financial statements included within this Annual Report on Form 10-K.

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 their evaluation, our principal executive officer and principal financial and accounting officer concluded that, as of December 31, 2022, 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, 2022.

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, 2022, 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 have concluded that our internal control over financial reporting was effective as of December 31, 2022.

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, 2022 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 established by the JOBS Act for emerging growth companies.

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 in our proxy statement related to the 2023 Annual Meeting of Stockholders currently scheduled to be held on June 12, 2023, or 2023 Proxy Statement, 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 2023 Proxy Statement.

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 2023 Proxy Statement.

The information required by this Item concerning compliance with Section 16(a) of the Exchange Act is incorporated by reference from the section of our 2023 Proxy Statement captioned "Delinquent Section 16(a) Reports."

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" in our 2023 Proxy Statement.

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

The following table provides information as of December 31, 2022 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	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders			
2014 Equity Incentive Plan, as amended	945,888	$ 3.06	104,342
Amended and Restated 2018 Omnibus Stock Incentive Plan	4,640,365	3.49	906,903
Equity compensation plans not approved by security holders	—	—	—
Total	5,586,253	$ 3.42	1,011,245

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 2023 Proxy Statement.

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" in our 2023 Proxy Statement.

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" in the proxy statement for the 2023 Annual Meeting of Stockholders.

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
3.2	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 A Warrant issued on March 24, 2020	8-K	001-38365	4.1	March 25, 2020
4.3	Form of Class b Warrant issued on March 24, 2020	8-K	001-38365	4.2	March 25, 2020
4.4	Form of Warrant issued on May 7, 2021	8-K	001-38365	4.1	May 10, 2021
4.5	Form of Pre-Funded Warrant issued on March 7, 2022	8-K/A	001-38365	4.1	March 9, 2022
4.6	Form of Warrant issued on March 7, 2022	8-K/A	001-38365	4.2	March 9, 2022
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
10.2*	Master Consulting Services Agreement, dated November 4, 2014, between Eyenovia, Inc. and Private Medical Equity, Inc.	S-1	333-222162	10.10	December 19, 2017
10.3*	Executive Employment Agreement, dated February 15, 2019, by and between the Company and Tsontcho Ianchulev	8-K	001-38365	10.16	February 19, 2019
10.4*	Executive Employment Agreement, dated February 15, 2019, by and between the Company and John Gandolfo	8-K	001-38365	10.17	February 19, 2019
10.5*	Executive Employment Agreement, dated February 15, 2019, by and between the Company and John Gandolfo	8-K	001-38365	10.19	February 19, 2019
10.6	Form of Nondisclosure, Assignment of Inventions and Noncompetition Agreement	8-K	001-38365	10.21	February 19, 2019
10.7*	Eyenovia, Inc. 2014 Equity Incentive Plan, as amended	S-8	333-233278	10.14	August 14, 2019
10.8*	Form of Nonqualified Stock Option Agreement	S-8	333-233278	10.15	August 14, 2019
10.9	Registration Rights Agreement, dated March 23, 2020, between Eyenovia, Inc. and the investors named therein	8-K	001-38365	10.23	March 25, 2020
10.10	Promissory Note and Agreement dated May 3, 2020	8-K	001-38365	10.24	May 8, 2020
10.11*	Eyenovia, Inc. Amended and Restated 2018 Omnibus Stock Incentive Plan	8-K	001-38365	10.1	June 17, 2022
10.12*	Form of Notice of Stock Option Grant and Award Agreement	8-K	001-38365	10.14	June 14, 2018
10.13*	Form of Restricted Stock Award Agreement	8-K	001-38365	10.15	June 14, 2018
10.14#	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
10.15#	License Agreement by and between Eyenovia, Inc. and Bausch Health Ireland Limited, dated October 9, 2020	8-K	001-38365	10.1	October 13, 2020

10.16*	First Amendment to Executive Employment Agreement, dated February 1, 2021, by and between the Company and Michael M. Rowe	8-K	001-38365	10.1	February 3, 2021
10.17#	Loan and Security Agreement, by and between Eyenovia, Inc. and Silicon Valley Bank, dated May 7, 2021	8-K	001-38365	10.1	May 10, 2021
10.18#	First Amendment to Loan and Security Agreement, by and between Eyenovia, Inc. and Silicon Valley Bank, dated September 29, 2021	10-Q	001-38365	10.3	November 12, 2021
10.19	Waiver Agreement, by and between Eyenovia, Inc. and Silicon Valley Bank, dated November 30, 2021	8-K	001-38365	10.1	December 3, 2021
10.20	Sales Agreement, by and between Eyenovia, Inc. and SVB Leerink LLC, dated December 14, 2021	S-3	333-261638	1.2	December 14, 2021
10.21	Securities Purchase Agreement by and between Eyenovia, Inc. and Armistice Capital Master Fund Ltd., dated March 3, 2022	8-K	001-38365	10.1	March 7, 2022
10.22	Director Compensation Policy	10-K	001-38365	10.22	March 30, 2022
10.23	Addendum to Executive Employment Agreement, dated March 10, 2022, by and between the Company and Tsontcho Ianchulev	10-K	001-38365	10.23	March 30, 2022
10.24	Addendum to Executive Employment Agreement, dated March 10, 2022, by and between the Company and John Gandolfo	10-K	001-38365	10.24	March 30, 2022
10.25	Addendum to Executive Employment Agreement, dated March 10, 2022, by and between the Company and Michael Rowe	10-K	001-38365	10.25	March 30, 2022
10.26	Third Amendment to Loan and Security Agreement, dated as of May 6, 2022, by and between Eyenovia, Inc. and Silicon Valley Bank.	8-K	001-38365	10.1	May 15, 2022
10.27*#	Employment Agreement, dated July 26, 2022, by and between Eyenovia, Inc, and Michael Rowe	10-Q	001-38365	10.2	August 11, 2022

10.28*	Executive Chair Agreement, dated August 1, 2022, by and between, Eyenovia, Inc. and Tsontcho Ianchulev	10-Q	001-38365	10.3	August 11, 2022
10.29	Non-Employee Director Compensation Policy, as amended	10-Q	001-38365	10.1	November 14, 202
10.30	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.	--	--	--	Filed herewith
10.31	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.	--	--	--	Filed herewith
10.32	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.	--	--	--	Filed herewith
10.33	Employment Agreement, dated December 19, 2022, by and between Eyenovia, Inc. and Bren Kern	--	--	--	Filed herewith
23.1	Consent of Marcum LLP	--	--	--	Filed herewith
31.1	Certification of the Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	--	--	--	Filed herewith
31.2	Certification of the 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

101	Inline interactive data files pursuant to Rule 405 of Regulation S-T: (i) Balance Sheets as of December 31, 2022 and 2021; (ii) Statements of Operations for the Years Ended December 31, 2022 and 2021; (iii) Statements of Changes in Stockholders' Equity for the Years Ended December 31, 2022 and 2021; (iv) Statements of Cash Flows for the Years Ended December 31, 2022 and 2021; 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) is 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: March 31, 2023

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 Officer) and Director	March 31, 2023
/s/ John Gandolfo John Gandolfo	Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2023
/s/ Tsontcho Ianchulev Tsontcho Ianchulev	Director	March 31, 2023
/s/ Rachel Jacobson Rachel Jacobson	Director	March 31, 2023
/s/ Charles E. Mather IV Charles E. Mather IV	Director	March 31, 2023
/s/ Ram Palanki Ram Palanki	Director	March 31, 2023
/s/ Ellen Strahlman Ellen Strahlman	Director	March 31, 2023

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, 2022 and 2021, the related statements of operations, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2022 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, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, 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 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.

Change in Accounting Principle

As discussed in Note 2 and Note 9 to the financial statements, the Company has changed its method of accounting for leases in 2022 due to the adoption of the guidance in ASC Topic 842, Leases effective January 1, 2022.

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 audits. 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.

/s/ Marcum LLP

Marcum LLP

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

New York, NY
March 31, 2023

EYENOVIA, INC.

Balance Sheets

	December 31,	
	2022	2021
Assets		
Current Assets:		
Cash and cash equivalents	$ 22,863,520	$ 19,461,850
Deferred clinical supply costs	2,284,931	—
License fee and expense reimbursements receivable	1,183,786	1,805,065
Security deposits, current	119,550	—
Prepaid expenses and other current assets	1,190,719	734,942
Total Current Assets	27,642,506	22,001,857
Restricted cash	—	7,875,000
Property and equipment, net	1,295,115	1,271,225
Security deposits, non-current	80,874	119,035
Operating lease right-of-use asset	1,291,592	—
Equipment deposits	726,326	391,941
Total Assets	$ 31,036,413	$ 31,659,058
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 1,428,283	$ 1,614,104
Accrued compensation	1,747,191	1,543,618
Accrued expenses and other current liabilities	503,076	845,719
Deferred rent - current portion	—	18,685
Operating lease liabilities - current portion	484,882	—
Notes payable - current portion, net of debt discount of $33,885 and $349,632 as of December 31, 2022 and 2021, respectively	174,448	7,150,368
Convertible notes payable - current portion, net of debt discount of $33,885 and $0 as of December 31, 2022 and 2021, respectively	174,448	—
Total Current Liabilities	4,512,328	11,172,494
Deferred rent - non-current portion	—	19,949
Operating lease liabilities - non-current portion	907,644	—
Notes payable - non-current portion, net of debt discount of $813,229 and $0 as of December 31, 2022 and 2021, respectively	4,190,938	—
Convertible notes payable - non-current portion, net of debt discount of $813,229 and $0 as of December 31, 2022 and 2021, respectively	4,190,938	—
Total Liabilities	13,801,848	11,192,443
Commitments and contingencies (Note 9)		
Stockholders' Equity:		
Preferred stock, $0.0001 par value, 6,000,000 shares authorized; 0 shares issued and outstanding as of December 31, 2022 and 2021, respectively	—	—
Common stock, $0.0001 par value, 90,000,000 shares authorized; 36,668,980 and 28,426,616 shares issued and outstanding as of December 31, 2022 and 2021, respectively	3,667	2,844
Additional paid-in capital	135,461,361	110,683,077
Accumulated deficit	(118,230,463)	(90,219,306)
Total Stockholders' Equity	17,234,565	20,466,615
Total Liabilities and Stockholders' Equity	$ 31,036,413	$ 31,659,058

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

EYENOVIA, INC.

Statements of Operations

	For the Years Ended December 31,	
	2022	**2021**
Operating Income		
Revenue	$ —	$ 14,000,000
Cost of revenue	—	(1,600,000)
Gross Profit	—	12,400,000
Operating Expenses:		
Research and development	13,378,680	14,850,874
General and administrative	13,532,835	10,569,653
Total Operating Expenses	26,911,515	25,420,527
Loss From Operations	(26,911,515)	(13,020,527)
Other Income (Expense):		
Extinguishment of PPP 7(a) loan	—	463,353
Other income, net	197,090	164,027
Interest expense	(1,380,058)	(387,756)
Interest income	83,326	2,516
Net Loss	$ (28,011,157)	$ (12,778,387)
Net Loss Per Share - Basic and Diluted	$ (0.83)	$ (0.49)
Weighted Average Number of Common Shares Outstanding - Basic and Diluted	33,649,747	26,324,081

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

EYENOVIA, INC.

Statements of Changes in Stockholders' Equity

	For the Years Ended December 31, 2022 and 2021				
	Common Stock		Additional Paid-In	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
Balance - January 1, 2021	24,978,585	$ 2,498	$ 92,742,306	$ (77,440,919)	$ 15,303,885
Issuance of common stock in At the Market offering [1]	2,435,604	244	12,401,675	—	12,401,919
Exercise of stock warrants	885,482	89	2,124,815	—	2,124,904
Exercise of stock options	121,261	12	203,114	—	203,126
Shares withheld from option exercise for employee tax liability	(13,675)	(1)	(26,323)	—	(26,324)
Issuance of SVB warrants [2]	—	—	351,390	—	351,390
Stock-based compensation	—	—	2,886,102	—	2,886,102
Issuance of common stock related to vested restricted stock units	19,359	2	(2)	—	-
Net loss	—	—	—	(12,778,387)	(12,778,387)
Balance - December 31, 2021	28,426,616	2,844	110,683,077	(90,219,306)	20,466,615
Issuance of common stock and warrants in direct offering [3]	3,000,000	300	14,897,608	—	14,897,908
Issuance of common stock in debt financing [4]	547,807	54	859,679	—	859,733
Origination costs related to equity in debt financing	—	—	(44,375)	—	(44,375)
Issuance of common stock in At the Market offering [5]	2,716,061	271	5,281,505	—	5,281,776
Exercise of stock warrants	1,870,130	187	18,514	—	18,701
Stock-based compensation	—	—	3,765,364	—	3,765,364
Issuance of common stock related to vested restricted stock units	108,366	11	(11)	—	—
Net loss	—	—	—	(28,011,157)	(28,011,157)
Balance - December 31, 2022	36,668,980	$ 3,667	$135,461,361	$(118,230,463)	$ 17,234,565

[1] Includes gross proceeds of $12,785,483, less total issuance costs of $383,564.
[2] Allocated fair value of warrants of $354,539, less allocated issuance costs of $3,149.
[3] Includes gross proceeds of $14,981,299 less total issuance costs of $83,391.
[4] Relative fair value of stock issued in connection with debt.
[5] Includes gross proceeds of $5,445,130, less total issuance costs of $163,354.

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

EYENOVIA, INC.

Statements of Cash Flows

	For the Years Ended December 31,	
	2022	**2021**
Cash Flows From Operating Activities		
Net loss	$ (28,011,157)	$ (12,778,387)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	3,765,364	2,886,102
Depreciation of property and equipment	307,430	221,563
Amortization of debt discount	411,918	68,376
Write-off of property and equipment	209,040	—
Gain on forgiveness of PPP 7(a) Loan	—	(463,353)
Non-cash rent expense	474,778	—
Expense reimbursement	—	(51,588)
Gain on disposal of property and equipment	—	(55,194)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	219,555	423,896
License fee and expense reimbursements receivables	621,279	1,397,924
Deferred clinical supply costs	(2,284,931)	—
Deferred license costs	—	1,600,000
Security deposits	(81,389)	—
Accounts payable	(185,821)	126,115
Accrued compensation	203,573	392,946
Accrued expenses and other current liabilities	(342,643)	(634,973)
Deferred license fee	—	(14,000,000)
Deferred rent	—	(7,859)
Lease liabilities	(412,478)	
Net Cash Used In Operating Activities	(25,105,482)	(20,874,432)
Cash Flows From Investing Activities		
Purchases of property and equipment	(540,360)	(1,226,576)
Vendor deposits for property and equipment	(334,385)	(391,941)
Net Cash Used In Investing Activities	(874,745)	(1,618,517)
Cash Flows From Financing Activities		
Proceeds from sale of common stock and warrants in direct offering [1]	14,981,299	—
Payment of issuance costs in registered direct offering	(83,391)	—
Proceeds from sale of common stock in At the Market offering	5,445,130	12,785,483
Payment of issuance costs for At the Market offering	(163,354)	(383,564)
Proceeds from exercise of stock warrants	18,701	2,124,904
Proceeds from SVB loan	—	7,500,000
Payment of SVB loan issuance costs	—	(66,618)
Proceeds from notes and equity issued to Avenue	10,000,000	—
Payment of issuance costs for equity issued to Avenue	(46,836)	—
Payment of issuance costs for notes issued to Avenue	(469,320)	—
Repayments of notes payable	(8,175,332)	(705,360)
Proceeds from exercise of stock options	—	203,126
Net Cash Provided By Financing Activities	21,506,897	21,457,971
Net Decrease in Cash and Cash Equivalents	(4,473,330)	(1,034,978)
Cash and cash equivalents - Beginning of Year	27,336,850	28,371,828
Cash and cash equivalents - End of Year	$ 22,863,520	$ 27,336,850

[1] Includes gross proceeds of $14,981,299, of which $5,741,299 is pre-funded warrants.

Cash, cash equivalents and restricted cash consisted of the following:		
Cash and cash equivalents	22,863,520	$ 19,461,850
Restricted cash	—	7,875,000
	$ 22,863,520	$ 27,336,850
Supplemental Disclosure of Cash Flow Information:		
Cash paid during the year for:		
Interest	$ 315,550	$ 227,171
Supplemental Disclosure of Non-Cash Investing and Financing Activities		
Purchase of insurance premium financed by note payable	675,332	$ 705,360
Recognition of right-of-use asset for lease liability upon adoption of ASU 2016-02	618,906	$ —
Right-of-use assets obtained in exchange for lease liabilities	1,186,098	$ —
Shares withheld from option exercise for employee tax liability	—	$ 26,324
Warrants issued for debt issuance costs	—	$ 351,390
Common shares issued recorded as debt discount for Avenue Loan	859,733	$ —
Issuance of common stock related to vested restricted stock units	11	$ 2

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

EYENOVIA, INC.
NOTES TO THE FINANCIAL STATEMENTS
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Note 1 – Business Organization and Nature of Operations

Eyenovia, Inc., or Eyenovia or the Company, is a pre-commercial ophthalmic technology company developing the Optejet® delivery system for use both in combination with its own drug-device therapeutic programs as well as out-licensing for additional indications. Eyenovia's aim is to improve the delivery of topical ophthalmic medication through ergonomic design that facilitates ease-of-use and delivery of more physiologically appropriate medication volume, with the goal to reduce side effects and improve tolerability, and introduce digital health technology to improve therapy compliance and ultimately medical outcomes. 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 faster than the blink reflex to help ensure instillation success. The precise delivery of a low-volume columnar spray by the Optejet® device minimizes contamination 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 ~ 50%. A more physiologically appropriate volume of medication in the range of seven to nine microliters is delivered by the Optejet, 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. Versions of the Optejet are being developed with on-board digital technology to provide reminders via Bluetooth to smart devices and date and time stamp device use. 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. To address unmet medical needs, the Company is developing the next generation of smart ophthalmic therapeutics to target new indications or new combinations where there are currently no or few drug therapies approved by the U.S. Food and Drug Administration, or FDA. The Company's investigational products are classified by the FDA as drug-device combination products with drug primary mode of action, meaning that the Center for Drug Evaluation and Research, or CDER, is designated as the lead center with primary jurisdictional oversight. Accordingly, the product candidates are submitted to the FDA and CDER for premarket review and approval under new drug applications, or NDAs.

Note 2 – Summary of Significant Accounting Policies

Liquidity and Going Concern

As of December 31, 2022, the Company had unrestricted cash and cash equivalents of approximately $22.9 million and an accumulated deficit of approximately $118.2 million. For the years ended December 31, 2022 and 2021, the Company incurred net losses of approximately $28.0 million and $12.8 million, respectively, and used cash in operations of approximately $25.1 million and $20.9 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. The Company expects that its research and development and general and administrative expenses will continue to increase and, as a result, it will eventually need to generate significant product revenues to achieve profitability. 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 or the Company's ability to raise further capital, through the sale of additional equity or debt securities 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 the adequacy of its available funds will depend on many factors, including the Company's 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 and take additional measures to reduce costs in order to conserve its cash.

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 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.

Reclassifications

Certain prior period balances have been reclassified in order to conform to current period presentation. These reclassifications have no effect on previously reported results of operations or loss per share.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents in the financial statements.

Cash and cash equivalents that are restricted as to withdrawal or use under the terms of certain executed agreements are recorded as restricted cash on the balance sheets. As of December 31, 2021, the Company had restricted cash in the amount of $7,875,000, which consisted of cash held in a money market account pledged as collateral for a note payable to Silicon Valley Bank, or the SVB Loan. The restricted cash was used in the repayment of the SVB Loan in November 2022. See Note 7 – Notes Payable and Convertible Notes Payable – Silicon Valley Bank Loan. As of December 31, 2022 and 2021, the Company had cash and cash equivalent balances in excess of FDIC insurance limits of $22,613,520 and $19,211,850, respectively.

On March 10, 2023, Silicon Valley Bank, or SVB, was closed by the California Department of Financial Protection and Innovation, and the Federal Deposit Insurance Corporation, or FDIC, was appointed as receiver. The Company has a deposit account at SVB. The standard deposit insurance amount is up to $250,000 per depositor, per insured bank, for each account ownership category. As of the date of filing, the Company had approximately $194,000 in a deposit account at SVB.

Property and Equipment, Net

Property and equipment are stated at cost, net of accumulated depreciation, 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.

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 did not record any impairment losses during the years ended December 31, 2022 and 2021.

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.

EYENOVIA, INC.
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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 general and administrative expenses in the statements of operations.

Revenue Recognition

The Company's revenues are generated primarily through 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 us 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;

EYENOVIA, INC.
NOTES TO THE FINANCIAL STATEMENTS
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- 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.

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, or Arctic Vision Amendment 1, pursuant to which Arctic Vision may develop and commercialize MicroStat for the treatment of mydriasis in Greater China and South Korea.

Upfront License Fees

During the year ended December 31, 2021, the Company recognized $4.0 million in revenue, pursuant to the Arctic Vision license agreement, upon the submission of certain trial data to Arctic Vision, permitting Arctic Vision to seek regulatory approval with the National Medical Products Administration of China.

Pursuant to the terms of the Senju License Agreement (see Note 10 – Related Party Transactions) the Company is required to pay Senju a percentage of payments received from Arctic Vision. Accordingly, the Company paid $1.6 million to Senju in connection with the $4.0 million upfront license fees received from Arctic Vision, which is reflected as cost of revenue in the accompanying statements of operations. In connection with Arctic Vision Amendment 1, Arctic Vision paid the Company a $250,000 upfront fee, which in turn, the Company paid to Senju in connection with Senju Amendment 2 (see Note 10 – Related Party Transactions). The Company did not recognize revenue for the $250,000 upfront payment because it was passed through to Senju.

Milestone Payments

The Company may receive an additional $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. The Company currently anticipates the remaining milestone related performance obligations to be achieved between late 2024 and late 2025.

EYENOVIA, INC.
NOTES TO THE FINANCIAL STATEMENTS
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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, 2022. 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 Agreement

On October 9, 2020, the Company entered into the Bausch License Agreement pursuant to which Bausch + Lomb may develop and commercialize the Bausch Licensed Product in the Licensed Territory. Bausch + Lomb may 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. Both parties have the right to terminate the Bausch License Agreement in the event of (i) an uncured material breach after a 60-day period or (ii) a bankruptcy event.

Upfront License Fees

During the year ended December 31, 2021, the Company recognized revenue of $10.0 million upon the submission of certain trial to Bausch + Lomb and the transfer of supervisory oversight of the clinical trial to Bausch + Lomb, permitting Bausch + Lomb to assume supervisory oversight of the ongoing MicroPine study, or the CHAPERONE study.

Milestone Payments

Bausch + Lomb could also pay the Company up to an aggregate of approximately $35.0 million in additional payments, depending on the achievement of certain regulatory and launch-based milestones. No milestone payments were earned through December 31, 2022. The Company currently anticipates that the aforementioned milestone payments will be earned between late 2024 and late 2025.

Royalty Payments

Under the terms of the Bausch License Agreement, on a country-to-country basis and Bausch Licensed Product-by- Bausch Licensed Product basis, Bausch + Lomb will pay the Company royalties on a tiered basis (ranging from mid-single digit to mid-teen percentages) on gross profits from the sales of the Bausch Licensed Product in the Licensed Territory, subject to certain adjustments in the event of generic entry, negative gross profits or patent expiration, for a period of the later to occur of the 10th anniversary of the first commercial sale of a Bausch Licensed Product in such country in the Licensed Territory or the expiration of the last valid patent claim for a Bausch Licensed Product in such country in the Licensed Territory. No royalty payments were earned through December 31, 2022.

Clinical Supply Arrangements

Bausch + Lomb and Arctic Vision have 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. Our licensing agreements with Bausch + Lomb and 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) to report the net income from the clinical supply arrangements as other income. Deferred clinical supply costs were $2.3 million at December 31, 2022. Net income from the sale of clinical supplies was included in other income and amounted to $0.2 million for the year ended December 31, 2022.

Operating Leases

The Company adopted the Accounting Standards Update, or ASU 2016-02,"Leases (Topic 842)" as of December 31, 2022, effective January 1, 2022. 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 ROU 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 11 – Stockholders' Equity – Stock Options for additional information related to estimating the fair value of stock options.

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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. 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,	
	2022	2021
Numerator:		
Net income (loss)	$ (28,011,157)	$ (12,778,387)
Net loss attributable to common stockholders	$ (28,011,157)	$ (12,778,387)
Denominator (weighted average quantities):		
Common shares issued	33,252,644	26,238,134
Add: Prefunded warrants	333,037	—
Add: Undelivered vested restricted shares	64,066	85,947
Denominator for basic and diluted net loss per share	33,649,747	26,324,081
Basic and diluted net loss per share of common stock	$ (0.83)	$ (0.49)

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,	
	2022	2021
Warrants	6,087,845	1,217,715
Options	5,380,553	4,377,398
Restricted stock units	172,800	41,778
Total potentially dilutive shares	11,641,198	5,636,891

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 Adopted Accounting Standards

On May 3, 2021, the Financial Accounting Standards Board, or the FASB, issued ASU No. 2021-04, “Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40): Issuer’s Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options.” This new standard provides clarification and reduces diversity in an issuer’s accounting for modifications or exchanges of freestanding equity-classified written call options (such as warrants) that remain equity classified after modification or exchange. This standard is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Issuers should apply the new standard prospectively to modifications or exchanges occurring after the effective date of the new standard. The Company adopted ASU 2021-04 effective January 1, 2022. This standard did not have a material impact on the Company’s financial position, results of operations or cash flow.

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In February 2016, the FASB issued ASU 2016-02 "Leases (Topic 842)", or ASU 2016-02. ASU 2016-02 requires that a lessee recognize the assets and liabilities that arise from operating leases. A lessee should recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term. ASU 2016-02, as amended, is now effective for emerging growth companies for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. The Company adopted ASU 2016-02 on December 31, 2022, effective January 1, 2022 and the adoption of this ASU had a material impact on the Company's financial statements, primarily as a result of recording right-of-use assets and lease liabilities for its operating leases in the approximate amounts of $580,000 and $619,000, and derecognizing deferred rent in the approximate amount of $39,000.

Recently Issued Accounting Standards

In June 2016, the FASB issued ASU No. 2016-13 "Financial Instruments - Credit Losses (Topic 326)" and also issued subsequent amendments to the initial guidance under ASU 2018-19, ASU 2019-04 and ASU 2019-05 (collectively Topic 326). Topic 326 requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. This replaces the existing incurred loss model with an expected loss model and requires the use of forward-looking information to calculate credit loss estimates. The Company will be required to adopt the provisions of this ASU on January 1, 2023, with early adoption permitted for certain amendments. Topic 326 must be adopted by applying a cumulative effect adjustment to retained earnings. The adoption of Topic 326 is not expected to have a material impact on the Company's financial position, results of operations or cash flows.

In August 2020, the FASB issued ASU 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging— Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, to clarify the accounting for certain financial instruments with characteristics of liabilities and equity. The amendments in this update reduce the number of accounting models for convertible debt instruments and convertible preferred stock by removing the cash conversion model and the beneficial conversion feature model. Limiting the accounting models will result in fewer embedded conversion features being separately recognized from the host contract. Convertible instruments that continue to be subject to separation models are (1) those with embedded conversion features that are not clearly and closely related to the host contract, that meet the definition of a derivative, and that do not qualify for a scope exception from derivative accounting and (2) convertible debt instruments issued with substantial premiums for which the premiums are recorded as paid-in-capital. In addition, this ASU improves disclosure requirements for convertible instruments and earnings-per-share guidance. The ASU also revises the derivative scope exception guidance to reduce form-over-substance-based accounting conclusions driven by remote contingent events. The amendments in this update are effective for the Company in fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. Early adoption is permitted, but not earlier than for fiscal years beginning after December 15, 2020. The Company early adopted ASU 2020-06 effective January 1, 2023 which eliminates the need to assess whether a beneficial conversion feature needs to be recognized upon the issuance of new convertible instruments. The adoption of ASU 2020-06 is not expected to have a material impact on the Company's financial position, results of operations or cash flows.

Note 3 – Prepaid Expenses and Other Current Assets

As of December 31, 2022 and 2021, prepaid expenses and other current assets consisted of the following:

	December 31,	
	2022	2021
Payroll tax receivable	$ 660,891	$ 343,785
Prepaid insurance expenses	201,082	171,370
Prepaid conference expenses	97,743	12,586
Prepaid general and administrative expenses	87,982	71,375
Prepaid rent and security deposit	74,959	32,254
Prepaid patent expenses	38,796	32,797
Other	26,745	4,525
Prepaid research and development expenses	2,521	—
Prepaid board of directors fees	—	66,250
Total prepaid expenses and other current assets	$ 1,190,719	$ 734,942

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Note 4 - Property and Equipment, Net

As of December 31, 2022 and 2021, property and equipment consisted of the following:

	December 31,	
	2022	2021
Equipment	$ 1,271,372	$ 854,060
Equipment not yet placed in service	90,411	254,864
Leasehold improvements	569,170	490,709
	1,930,953	1,599,633
Less: accumulated depreciation and amortization	(635,838)	(328,408)
Property and equipment, net	$ 1,295,115	$ 1,271,225

Depreciation expense was $307,430 and $221,563 for the years ended December 31, 2022 and 2021, respectively, of which $301,205 and $211,604, respectively, was included within research and development expenses and $6,225 and $9,959, respectively, was included in general and administrative expenses in the accompanying statements of operations.

As of December 31, 2022 and 2021, the Company had $726,326 and $391,941 of outstanding deposits for equipment purchases.

Note 5 – Accrued Expenses and Other Current Liabilities

As of December 31, 2022 and 2021, accrued expenses and other current liabilities consisted of the following:

	December 31,	
	2022	2021
Accrued consulting and professional services	$ 320,000	$ 250,000
Accrued leasehold improvements	92,528	—
Credit card payable	50,639	20,000
Accrued research and development expenses	35,524	436,840
Other	4,385	42,407
Accrued interest	—	94,792
Accrued franchise tax	—	1,680
Total accrued expenses and other current liabilities	$ 503,076	$ 845,719

Note 6 – Accrued Compensation

As of December 31, 2022 and 2021, accrued compensation consisted of the following:

	December 31,	
	2022	2021
Accrued bonus expenses	$ 1,447,643	$ 1,245,795
Accrued payroll expenses	299,548	297,823
Total accrued compensation	$ 1,747,191	$ 1,543,618

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Note 7 – Notes Payable and Convertible Notes Payable

As of December 31, 2022 and 2021, notes payable and convertible notes payable consisted of the following:

	December 31, 2022			December 31, 2021		
	Notes Payable	Debt Discount	Net	Notes Payable	Debt Discount	Net
Silicon Valley Bank loan	$ —	$ —	$ —	$ 7,500,000	$ (349,632)	$ 7,150,368
Avenue - Note payable	5,212,500	(847,114)	4,365,386	—	—	—
Avenue - Convertible note payable	5,212,500	(847,114)	4,365,386	—	—	—
Total	10,425,000	(1,694,228)	8,730,772	7,500,000	(349,632)	7,150,368
Less: Current portion						
Silicon Valley Bank loan	—	—	—	(7,500,000)	349,632	$ (7,150,368)
Avenue - Note payable	(208,333)	33,885	(174,448)	—	—	—
Avenue - Convertible note payable	(208,333)	33,885	(174,448)	—	—	—
Notes Payable, Non-Current	$ 10,008,334	$ (1,626,458)	$ 8,381,876	$ —	$ —	$ —

The non-current portion of notes payable and convertible notes payable includes a notes payable and a convertible note payable, each in the amount, net of discount, of $4,190,938.

BankDirect Capital Finance Loan

On February 24, 2021, the Company issued a note payable for the purchase of a directors and officers' liability insurance policy. The note payable was payable in nine monthly payments consisting of principal and interest amounting to $79,343 for an aggregate amount of $714,087. The note accrued interest at a rate of 2.96% per year and matured on November 24, 2021.The note payable was repaid in full during the year ended December 31, 2021. Interest expense was $8,727 for the year ended December 31, 2021.

On February 24, 2022, the Company issued a note payable for the purchase of a directors and officers' liability insurance policy. The note payable was payable in six monthly payments consisting of principal and interest amounting to $113,628 for an aggregate amount of $681,768. The note accrued interest at a rate of 3.26% per year and matured on August 24, 2022. The note payable was repaid in full during the year ended December 31, 2022. Interest expense was $6,436 for the year ended December 31, 2022.

Paycheck Protection Program Loan

On May 8, 2020, the Company received cash proceeds of $463,353 pursuant to a loan provided in connection with the Paycheck Protection Program under the CARES Act, or the PPP Loan. The PPP Loan provided for monthly installment payments of $19,508 beginning in August 2021 with the remaining balance due on May 3, 2022, the original maturity date. The PPP Loan incurred interest at a fixed rate of 1.00% per annum.

Under the terms of the CARES Act, as amended by the Paycheck Protection Program Flexibility Act of 2020, the Company was eligible to apply for and receive forgiveness for all or a portion of its PPP Loan. The Company applied for loan forgiveness on the PPP Loan in March 2021. The Company received notification in August 2021 that it had received approval for full loan forgiveness of the PPP Loan in the amount of $463,353. The Company has recorded this extinguishment as other income in the statements of operations for the year ended December 31, 2021. The Company also received notification of forgiveness of accrued interest payable of $5,738, which was reversed from interest expense.

Silicon Valley Bank Loan

On May 7, 2021, or the Effective Date, the Company entered into a Loan and Security Agreement, or the Loan, with Silicon Valley Bank, or SVB, for an aggregate principal amount of up to $25.0 million. The interest rate on the Loan was an annual rate equal to the greater of (a) the sum of 1.25% plus the prime rate as reported in The Wall Street Journal and (b) 5.00%. The initial tranche of the Loan, in the amount of $7.5 million was received by the Company on May 7, 2021. The maturity date of the Loan was May 1, 2025. The Loan

indicated a prepayment fee of 2.0% of the principal balance made on or prior to the second anniversary of the Effective Date. The Loan also provided for a final payment in an amount equal to the original aggregate principal amount of the Loan multiplied by 5.0%. The final payment is in addition to and not a substitution for the regular monthly payments of principal plus accrued interest and was due upon the repayment of the loan in full.

On September 29, 2021, the Company and SVB executed the First Amendment to the Loan and Security Agreement, or the Amendment. In accordance with the Amendment, the Company was required to maintain a collateralized money market account in the amount of $7,875,000. The Company recorded this amount as restricted cash. On October 25, 2021, the Company announced the reclassification of Mydcombi as a drug-device combination product by the FDA in a CRL received on October 22, 2021. Given the FDA's recent reclassification of Mydcombi as a drug-device combination and the need to file an NDA resubmission in 2022, the restricted cash became callable on November 30, 2021, at SVB's election, to satisfy the Loan obligations. Therefore, the Loan was fully classified as a current note payable as of December 31, 2021.

In connection with the Loan, the Company issued warrants to SVB to purchase 91,884 shares of common stock at an exercise price per share equal to $4.76. The warrants are exercisable for a period of ten years from the date of issuance. The Company determined that the warrants should be equity-classified and that the relative fair value was $354,539, by using the Black-Scholes option pricing methodology using the following assumptions: stock price of $4.76; expected term of 10.0 years; volatility of 89.0% and a risk-free interest rate of 1.60%. The Company incurred $66,618 of debt issuance costs, of which $63,469 was allocated to the debt and $3,149 was allocated to the warrants. The relative fair value of the warrants and the issuance costs allocated to the debt were recorded as debt discount.

On November 4, 2022, the Company repaid the SVB Loan in full. The full amount of the payment was $8,025,000, and included the principal amount of the loan ($7,500,000), the final payment ($375,000) and a 2% prepayment fee ($150,000). The final payment and prepayment fee were recorded as interest expense. The entire restricted cash account in the amount of $7,875,000 was used to make the substantial amount of the payment.

During the years ended December 31, 2022 and 2021, the Company recorded interest expense relating to the Loan of $1,174,736 and $317,333, respectively, including the amortization of debt discount of $349,632 and $68,376, respectively.

Avenue Ventures Loan

On November 22, 2022, the Company entered into a Loan and Security Agreement, or the Avenue Loan, with Avenue Venture Opportunities Fund, L.P., or Avenue 1, and Avenue Venture Opportunities Fund, L.P. II, or Avenue 2, and together with Avenue, the Lender, for an aggregate principal amount of up to $15,000,000. The initial tranche of the Avenue Loan is $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 $2.148 per share, subject to typical anti-dilution adjustments, or the Convertible Loan. 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 may 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, or the Final Payment, amounting to a premium of $425,000.

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.

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 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.

The Company paid a portfolio management fee of 1% of the total commitment of $15,000,000, or $150,000 of cash on December 1, 2022. This has been accounted for as a component of debt discount.

In connection with the Loan, the Company granted an aggregate of 547,807 shares of its common stock to the Lender, or the Avenue Private Placement Shares. Based on the Company's stock price of $1.79 per share on the closing date, the shares have a gross value of $980,575 and a relative fair value of $859,734. This is accounted for as a component of debt discount.

The following is a breakdown of the allocation of debt discount and origination costs:

		Allocation of Debt Discount					
	Allocation %	Withheld From Proceeds	Eyenovia Origination Costs	Premium-(Final Payment)	Equity Issued	Total Debt Discount	Equity Issuance Costs
Non-Convertible Note	45.70 %	$ 127,916	$ 107,976	$ 212,500	$ 429,867	$ 878,258	$ —
Convertible Note	45.70 %	127,916	107,976	212,500	429,867	878,258	—
Private Placement Shares	8.60 %	24,063	20,312	—	—	—	44,376
Total	**100.00 %**	**$ 279,895**	**$ 236,264**	**$ 425,000**	**$ 859,734**	**$ 1,756,516**	**$ 44,376**

Withheld From Closing Proceeds:	
Broker Fee	$ 250,000
Legal Reimbursement	29,895
Total	**$ 279,895**

Eyenovia Origination Costs:	
Legal Fee	$ 86,264
Avenue Management Fee	150,000
Total	**$ 236,264**

Total debt discount of $1,756,516 less the current year amortization of the Avenue loan in the amount of $62,288 resulted in unamortized debt discount of $1,694,228 at December 31, 2022.

The following is a summary of the Avenue loan:

	December 31, 2022		
	Non-Convertible	Convertible	Total
Initial loan funding	$ 5,000,000	$ 5,000,000	$ 10,000,000
Final payment	212,500	212,500	425,000
	5,212,500	5,212,500	10,425,000
Less: Unamortized debt discount	(847,114)	(847,114)	(1,694,228)
	4,365,386	4,365,386	8,730,772
Less: Current portion	(174,448)	(174,448)	(348,896)
Notes Payable, Non-Current	$ 4,190,938	$ 4,190,938	$ 8,381,876

During the year ended December 31, 2022, the Company recorded interest expense relating to the Loan of $189,510, including the amortization of debt discount of $62,288.

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Note 8 – Income Taxes

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

	For The Years Ended December 31,	
	2022	2021
Deferred tax provision (benefit):		
Federal	5,879,362	(1,248,043)
State and local	(208,806)	(2,358,623)
	5,670,556	(3,606,666)
Change in valuation allowance	(5,670,556)	3,606,666
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,	
	2022	2021
Federal statutory rate	(21.0)%	(21.0)%
State tax rate, net of federal benefit	(2.5)%	(7.3)%
Permanent differences	1.6 %	4.3 %
Research & development tax credits	(1.0)%	(0.6)%
Prior period adjustments and other	1.3 %	0.2 %
Rate and apportionment changes	1.3 %	(3.8)%
Change in valuation allowance	20.3 %	28.2 %
Effective income tax rate	(0.0)%	(0.0)%

Deferred tax assets consist of the following:

	For The Years Ended December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 20,165,693	$ 17,415,488
Research and development tax credits	799,182	605,919
Capitalized research and development costs	2,304,110	—
Stock-based compensation	2,089,014	2,070,759
Intangible assets	633,151	531,454
Lease liability	327,276	—
Total gross deferred tax assets	26,318,426	20,623,620
Deferred tax liabilities		
Property and equipment	(184,138)	(463,442)
Right ot use asset	(303,554)	—
Deferred tax assets, net before allowance	25,830,734	20,160,178
Valuation allowance	(25,830,734)	(20,160,178)
Deferred tax assets, net	$ —	$ —
Changes in valuation allowance	$ (5,670,556)	$ 3,606,666

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As of December 31, 2022, the Company had approximately $85,900,000 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 $75,100,000 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, 2022, the Company had approximately $25,400,000 of state NOLs, of which approximately $25,300,000 will expire during the years ranging from 2040 to 2042, and approximately $100,000 will not expire, and had approximately $6,400,000 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, 2022 and 2021, 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, 2022 and 2021. 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, 2022 and 2021. No tax related interest or penalties were incurred during the years ended December 31, 2022 and 2021. The Company's federal, state and local income tax returns beginning with the year ended December 31, 2019 remain subject to examination.

Note 9 – Commitments and Contingencies

Employment Agreements

On February 14, 2022, the Compensation Committee of the Board approved amendments to the Executive Employment Agreements, or the Employment Agreement Addendums, for three executive officers. Each of the Employment Agreement Addendums provides that if the executive's employment is terminated by the Company without "Cause" or the executive suffers an "Involuntarily Termination" (each as defined in the employment agreements), provided that the executive has signed a full release of all claims, the executive will be entitled to receive: (i) severance pay equal to twelve months of his or her then-current base salary, and (ii) a reimbursement for health insurance benefits under COBRA for the executive and his or her spouse and dependents for a period of twelve months or until the executive becomes eligible for comparable insurance benefits from another employer, whichever is earlier.

Transition of Chief Executive Officer

On July 27, 2022, the Company announced the appointment of Michael Rowe as its new Chief Executive Officer, or CEO, effective August 1, 2022, with Dr. Tsontcho Ianchulev (the former CEO) becoming Executive Chairman of the Board. Mr. Rowe is also serving as a member of the Board.

On July 26, 2022, the Company entered into an Employment Agreement, or the Employment Agreement, with Mr. Rowe under which he will serve as Chief Executive Officer of the Company. Under the terms of the Employment Agreement, Mr. Rowe will receive an annual salary of $575,000. He is eligible to receive a cash bonus of up to 60% of his base salary. Additionally, Mr. Rowe received an option to purchase 440,000 shares of the Company's common stock, exercisable at $1.66 per share, pursuant to the Company's Amended and Restated 2018 Omnibus Stock Incentive Plan, as amended. Mr. Rowe will also continue to participate in any and all benefit plans, from time to time, in effect for senior management, along with vacation, sick and holiday pay in accordance with the Company's policies established and in effect from time to time. As a result of the change of salary, the aggregate potential severance pay for the executive officers of the Company is approximately $1,004,000.

The Company also entered into an agreement with Dr. Ianchulev, or the Executive Chairman Agreement, pursuant to which Dr. Ianchulev will 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. In consideration for Dr. Ianchulev's services, the

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Company has 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.

Operating Leases

On August 8, 2018, the Company entered into a lease agreement to lease approximately 3,800 square feet of office space in New York, NY. The monthly base rent ranges from $19,633 to $22,486 per month over the term of the lease. The lease expires on September 30, 2023. The security deposit is approximately $118,000, which has been classified as a current asset. The Company's rent expense for this space is recorded in general and administrative expense and amounted to $242,067 for each of the years ended December 31, 2022 and 2021, respectively.

On January 20, 2020, the Company entered into a lease agreement to lease 660 square feet of office space in Laguna Hills, California. The lease term was one year and the lease was renewed each year until it expired on April 30, 2022. The monthly base rent ranged from $1,254 to $1,292 per month over the term of the lease. The Company received its $1,254 security deposit after the lease expired. The Company had also agreed to lease the adjoining premises as part of the lease extension. The additional office space is also 660 square feet. The lease term for this space expires April 30, 2023. The monthly rent ranges from $1,750 to $1,838 per month. The security deposit is $1,750 and has been classified as a current asset. The Company's rent expense for the space in this location is recorded in general and administrative expense and amounted to $20,501 and $29,424 for the years ended December 31, 2022 and 2021, respectively.

On April 8, 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 general and administrative expense and amounted to $66,196 and $0 for the years ended December 31, 2022 and 2021, respectively.

On July 17, 2020, the Company entered into a lease agreement to lease approximately 3,000 square feet of office space in Redwood City, California, or the Gross Industrial Lease. The monthly base rent was for $7,500 per month over the term of the lease through August 31, 2021 with a security deposit of $7,500. On December 1, 2020, the Company agreed to amend the terms of the Gross Industrial Lease for a base rent that ranges from $7,500 to $7,957 per month over the term of the lease. The amended Gross Industrial Lease expires on August 31, 2023. Concurrent with the amendment to the Gross Industrial Lease on December 1, 2020, the Company entered into a lease agreement to lease approximately 1,500 square feet of additional office space in Redwood City, California. The monthly base rent ranges from $3,000 to $3,183 per month over the term of the lease. The lease expires on August 31, 2023. The security deposit is $3,000. Also concurrent with the amendment to the Gross Industrial Lease on December 1, 2020, the Company entered into an additional lease agreement to lease 2,169 square feet of additional office space in Redwood City, California. The monthly base rent ranges from $4,468 to $4,602 per month over the term of the lease. The lease commenced on January 1, 2022 and expires on August 31, 2023. The security deposit is $4,468. The Company's rent expense for all Redwood City space is recorded in research and development expense and amounted to $180,240 and $128,560 for the years ended December 31, 2022 and 2021, respectively.

The Company leases 953 square feet of office space in Reno, NV for research and development activities from a company owned by the Company's former Vice President of Research and Development. The lease, as amended in September 2022, expires on May 1, 2023 and provides for lease payments of $5,675 per month and a security deposit in the amount of $5,675. Since the inception of the lease, the Company made $112,600 of leasehold improvements related to this lease which are included in property and equipment, net on the accompanying balance sheets. The Company's rent expense for this space is recorded in research and development expense and amounted to $68,498 and $64,848 for the years ended December 31, 2022 and 2021, respectively.

On May 19, 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 $101,023 for the year ended December 31, 2022.

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

	For the Year Ended December 31, 2022
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows used in operating activities	$ 412,478
Right-of-use assets obtained in exchange for lease obligations	
Operating leases	$ 1,186,098
Weighted Average Remaining Lease Term (Years)	
Operating leases	3.71 years
Weighted Average Discount Rate	
Operating leases	10.0 %

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

For the Year Ending December 31,	Minimum Lease Payments
2023	$ 588,181
2024	278,254
2025	289,887
2026	302,039
2027	216,126
Total lease payments	1,674,487
Less: Imputed interest	(281,961)
Present value of lease liabilities	1,392,526
Less: current portion	(484,882)
Lease liabilities, non-current portion	$ 907,644

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.

Note 10 – Related Party Transactions

See Note 9 - Commitments and Contingencies for certain commitments and contingencies entered into with certain related parties.

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.

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On April 8, 2020, Eyenovia entered into an amendment, or 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, or the 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.

See Note 2 – Summary of Significant Accounting Policies – Revenue Recognition - Arctic Vision License Agreement for additional details regarding the Arctic Vision License Agreement.

Note 11 – Stockholders' Equity

Authorized Capital

The Company is authorized to issue 90,000,000 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.

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, 5,700,000 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, 2022, the number of securities remaining available for future issuance under equity compensation plans was 1,011,245.

At-The-Market Offering

May 2021 Sales Agreement

On May 14, 2021, the Company entered into a Sales Agreement, or the May 2021 Sales Agreement with SVB Securities LLC, or SVB Securities (formerly known as SVB Leerink LLC), under which the Company was able to offer and sell, from time to time at its sole discretion, shares of its common stock having an aggregate offering price of up to $30 million through SVB Securities as its sales agent. Subject to the terms and conditions of the May 2021 Sales Agreement, SVB Securities was able to 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 was obligated to 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 had to 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 May 2021 Sales Agreement.

Pursuant to the May 2021 Sales Agreement, the Company commenced sales of its common stock on October 6, 2021. During the year ended December 31, 2021, the Company received approximately $12.8 million in gross proceeds and $12.4 million in net proceeds from the sale of 2,435,604 shares of its common stock under the May 2021 Sales Agreement.

December 2021 Sales Agreement

On December 14, 2021, the Company entered into a Sales Agreement, or 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 Offering. The May 2021 Sales Agreement was terminated upon the effectiveness of the December 2021 Sales Agreement. 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 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, 2022, the Company received approximately $5.4 million in gross proceeds and $5.3 million in net proceeds from the sale of 2,716,061 shares of its common stock under the December 2021 Sales Agreement.

Securities Purchase Agreement

On March 3, 2022, the Company entered into a securities purchase agreement, or the Purchase Agreement with a certain institutional and accredited investor, or the Purchaser, pursuant to which the Company issued (i) 3,000,000 shares of common stock, (ii) pre-funded warrants, or the Pre-Funded Warrants, to purchase an aggregate of 1,870,130 shares of common stock and (iii) warrants to purchase an aggregate of 4,870,130 shares of common stock, or the Investor Warrants, or the March 2022 Offering. The Company determined that the warrants qualified for equity classification.

The offering price for the shares was $3.08 per share and the offering price for the Pre-Funded Warrants was $3.07 per Pre-Funded Warrant, which represents the per share public offering price less $0.01 per share exercise price for each Pre-Funded Warrant. The Investor Warrants will have an exercise price of $3.54 per share and each Investor Warrant will be exercisable for one share of Common Stock. The Investor Warrants will be exercisable beginning six months from the date of issuance and the Pre-Funded Warrants will be exercisable immediately upon issuance. The Pre-Funded Warrants shall terminate when fully exercised and the Investor Warrants will

terminate five years from the initial exercisability date. The aggregate gross proceeds to the Company from the March 2022 Offering were approximately $15 million, excluding the proceeds, if any, from the exercise of the Pre-Funded Warrants and the Investor Warrants. No underwriter or placement agent participated in the March 2022 Offering. The Company incurred issuance costs in the amount of $89,031 in connection with the March 2022 offering.

The March 2022 Offering was made pursuant to an effective registration statement on Form S-3 (Registration Statement No. 333-261638), as previously filed with and declared effective by the Securities and Exchange Commission and a related prospectus.

Warrants

A summary of the warrant activity during the year ended December 31, 2022 is presented below:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Aggregate Intrinsic Value
Outstanding January 1, 2022	1,217,715	$ 2.69		
Granted	6,740,260	2.56		
Exercised	(1,870,130)	0.01		
Outstanding December 31, 2022	6,087,845	$ 3.37	4.3	$ —
Exercisable December 31, 2022	6,087,845	$ 3.37	4.3	$ —

The following table presents information related to warrants as of December 31, 2022:

Warrants Outstanding		Warants Exercisable	
Exercise Price	Outstanding Number of Warrants	Weighted Average Remaining Life In Years	Exercisable Number of Warrants
$2.4696	909,451	2.2	909,451
$2.7240	216,380	2.2	216,380
$4.7600	91,884	8.3	91,884
$3.5400	4,870,130	4.7	4,870,130
	6,087,845	4.3	6,087,845

During the year ended December 31, 2022, warrants for the purchase of 1,870,130 shares of the Company's common stock with an exercise price $0.01 per share were exercised for aggregate proceeds of $18,701.

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, 2022 and 2021, the Company recorded stock-based compensation expense of $3,765,364 ($1,809,305 of which was included within research and development expenses and $1,956,059 was included within general and administrative expenses on the statements of operations) and $2,886,102 ($1,612,942 of which was included within research and development expenses and $1,273,160 was included within general and administrative expenses on the statements of operations), respectively.

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Restricted Stock Units

A summary of the restricted stock units activity during the year ended December 31, 2022 is presented below:

	Number of RSUs	Exercise Price
RSUs non-vested January 1, 2022	41,778	$ 3.59
Granted	193,304	1.93
Vested	(55,319)	3.37
Forfeited	(6,963)	3.59
RSUs non-vested December 31, 2022	172,800	$ 1.80
Vested RSUs undelivered December 31, 2022	32,900	$ 3.59

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.

Between March 31, 2021 and November 17, 2021 the Company granted members of its Board of Directors an aggregate of 49,964 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) June 16, 2022 (the date of the 2022 annual stockholders meeting), subject to the grantee remaining on the Board until then. The RSUs had a grant date fair value of $181,200, which will be recognized over the vesting period.

Between February 14, 2022 and August 18, 2022 the Company granted members of its Board of Directors an aggregate of 193,304 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 2023 annual stockholders meeting, subject to the grantee remaining on the Board until then. The RSUs had a grant date fair value of $373,000, which will be recognized over the vesting period.

As of December 31, 2022, there was $149,158 of unrecognized stock-based compensation expense related to RSUs which will be recognized over a weighted average period of 0.5 years.

Stock Options

A summary of the option activity during the year ended December 31, 2022 is presented below:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Life In Years	Aggregate Intrinsic Value
Outstanding, January 1, 2022	4,377,398	$ 3.89		
Granted	1,181,310	2.23		
Exercised	—	—		
Forfeited	(178,155)	3.01		
Outstanding, December 31, 2022	5,380,553	$ 3.55	7.2	$ 85,800
Exercisable, December 31, 2022	3,614,195	$ 3.79	6.4	$ 85,800

EYENOVIA, INC.
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The following table presents information related to stock options as of December 31, 2022:

Options Outstanding			Options Exercisable
Exercise Price	Outstanding Number of Options	Weighted Average Remaining Life In Years	Exercisable Number of Options
$1.00 - $1.99	1,517,952	3.8	754,302
$2.00 - $2.99	1,010,018	7.4	847,485
$3.00 - $3.99	1,202,539	6.8	804,840
$4.00 - $4.99	383,500	8.5	193,623
$5.00 - $5.99	100,805	6.0	83,972
$6.00 - $6.99	1,000,821	7.0	765,055
$7.00+	164,918	5.3	164,918
	5,380,553	6.4	3,614,195

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,	
	2022	2021
Expected term (years)	0.58 - 10.00	5.85 - 10.00
Risk free interest rate	0.76% - 3.80%	0.45% - 1.58%
Expected volatility	82% - 90%	92% - 94%
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 a blended volatility calculation, the components of which are the Company’s historical volatility for the period from its initial public offering through the valuation date and the average peer-group data of six comparable entities to supplement the Company’s own historical data for the preceding years in computing the expected volatility. Accordingly, the Company is utilizing an expected volatility figure based on a review of the historical volatility of comparable entities 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, 2022 and 2021 was approximately $1.60 and $5.39 per share, respectively.

As of December 31, 2022, there was $3,621,440 of unrecognized stock-based compensation expense related to stock options which will be recognized over a weighted average period of 1.5 years.

Note 12 – 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. For 2019, the Company’s Board of Directors has 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, 2022 and 2021, the Company recorded expense of $208,006 and $175,352 associated with its matching contributions, respectively.

Note 13 – Subsequent Events

Stock Option Grants

Subsequent to December 31, 2022, the Company issued ten-year stock options to certain employees and consultants to purchase an aggregate of 421,735 shares of common stock of the Company at an exercise price $2.16 per share. The options vest as follows: (i) one-third of the shares vest on the one-year anniversary of the issuance date; and (ii) the remaining two-thirds vest in equal installments beginning 13 months from the issuance date and ending 36 months from the issuance date. The fair value of the options will be recognized over the vesting period.

December 2021 Sales Agreement

Subsequent to December 31, 2022, the Company received approximately $3.5 million of net proceeds from the sale of 1,299,947 shares of its common stock pursuant to the December 2021 Sales Agreement with SVB Securities.

Development Collaboration Agreement With Formosa

On February 15, 2023, the Company announced that they had entered into a Development Collaboration Agreement, or the Agreement with Formosa Pharmaceuticals, Inc., or Formosa, a Taiwan-based company. The Agreement combines the Company's Optejet dispensing technology with Formosa's unique APNT nanoparticle formulation platform for the potential development of new topical ophthalmic therapeutics that employ the Optejet dispenser. In 2023, the Company will conduct feasibility testing of novel APNT formulations in the Optejet and request a pre-IND meeting with the FDA. Formosa will develop and optimize new APNT formulations for use in Optejet and deliver to the Company for device qualification and validation.

Appointment of Chief Operating Officer

Effective January 1, 2023, the Company appointed Bren Kern, the Company's Senior Vice President of Manufacturing and Operations, as the Company's Chief Operating Officer. The Company entered into an Employment Agreement with Mr. Kern, under which Mr. Kern receives an annual salary of $345,000. He is eligible to receive a cash bonus of up to 30% of his base salary. Additionally, Mr. Kern received an option to purchase 120,000 shares of its common stock.

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

Our authorized capital stock consists of 90,000,000 shares of common stock, $0.0001 par value per share, and 6,000,000 shares of undesignated preferred stock, par value $0.0001 per share. The following description summarizes the material terms of our capital stock. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description of our capital stock, you should refer to our amended and restated certificate of incorporation, as amended (our "restated certificate"), and our amended and restated bylaws (our "restated bylaws"), which are included as exhibits to this Annual Report on Form 10-K, and to the provisions of applicable Delaware law.

Common Stock

As of December 31, 2022, there were 36,668,980 shares of our common stock outstanding. Holders of our common stock are entitled to the following rights.

- *Dividend Rights*. Subject to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of outstanding shares of our common stock are entitled to receive dividends out of funds legally available at the times and in the amounts that our board of directors may determine.

- *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, including the election of directors. Our restated certificate and restated bylaws do not provide for cumulative voting rights.

- *No Preemptive or Similar Rights*. The holders of our common stock have no preemptive, conversion, or subscription rights, and there are no redemption provisions applicable to our common stock.

- *Right to Receive Liquidation Distributions*. Upon our liquidation, dissolution or winding-up, the assets legally available for distribution to our stockholders would be distributable ratably among the holders of our common stock and any participating preferred stock outstanding at that time after payment of liquidation preferences, if any, on any outstanding shares of preferred stock and payment of other claims of creditors.

- *Fully Paid and Non-Assessable*. All of the outstanding shares of our common stock are fully paid and non-assessable.

- *Potential Adverse Effect of Future Preferred Stock*. The rights, preferences and privileges of the holders of common stock are subject to, and might be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Preferred Stock

Our board of directors is authorized, subject to limitations prescribed by Delaware law, to issue up to 6,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each series, and to fix the designation, powers, preferences and rights of the shares of each series and any of its qualifications, limitations or restrictions, in each case without further action by our stockholders. Our board may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring, or preventing a change in our control or the removal of management and might adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. As of December 31, 2022, no shares of our preferred stock were outstanding.

Stock Awards Available For Issuance

As of December 31, 2022, the Company has an aggregate of 1,011,245 shares of common stock available under our 2014 Equity Incentive Plan and Amended and Restated 2018 Omnibus Stock Incentive Plan.

CERTAIN PROVISIONS OF DELAWARE LAW, OUR RESTATED CERTIFICATE AND RESTATED BYLAWS

The provisions of Delaware law, our restated certificate, and our restated bylaws may have the effect of delaying, deferring, or discouraging another person from acquiring control of our Company.

Delaware Law. We are governed by the provisions of Section 203 of the Delaware General Corporation Law, or DGCL. In general, Section 203 prohibits a public 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 became an interested stockholder unless:

- prior to such time, the board of directors approved either the business combination or the transaction which 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 voting stock of the corporation outstanding at the time the transaction commenced, excluding shares owned by persons who are directors and also officers and by specified employee stock plans; or

- at or subsequent to the date of the transaction, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

A "business combination" includes mergers, asset sales or other transactions resulting in a financial benefit to the stockholder. In general, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years did own, 15% or more of the corporation's outstanding voting stock. These provisions may have the effect of delaying, deferring, or preventing a change in our control. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our board of directors does not approve in advance. We also anticipate that DGCL Section 203 may also discourage attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

Restated Certificate and Restated Bylaw Provisions. Various provisions of our restated certificate and restated bylaws could deter hostile takeovers or delay or prevent changes in control of our management team, including the following:

- Board of Directors Vacancies. Our restated certificate and restated bylaws authorize only our board fill vacant directorships. In addition, the number of directors constituting our board is permitted to be set only by a resolution adopted by a majority of our board. These provisions would prevent a stockholder from increasing the size of our board and then gaining control of our board by filling the resulting vacancies with its own nominees.

- Stockholder Action; Special Meeting 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 restated bylaws further provide that special meetings of our stockholders may be called only our board, President, Chief Executive Officer or by such other person the board expressly authorizes to call a special meeting.

- Our restated bylaws provide advance notice procedures for stockholders seeking to bring business before our annual meeting of stockholders. To be timely, a stockholder's notice must be delivered to, or mailed and received at, our principal executive offices not less than 90 days nor more than 120 days prior to the one-year anniversary of the previous year's annual meeting of stockholders; provided, that if no annual meeting of stockholders was held in the previous year or the date of the annual meeting of stockholders has been changed to be more than 30 calendar days earlier or 60 days later than such anniversary, notice by the stockholder, to be timely, must be received not earlier than the 120th day nor later to the 90th day prior to the date of such annual meeting or, if later, the 10th day following the date we publicly disclose the date of the annual meeting. Our restated bylaws also specify certain requirements regarding the form and content of a stockholder's notice. These provisions might preclude our stockholders from bringing matters before our annual meeting of stockholders.

- Our restated bylaws provide advance notice procedures for stockholders to nominate candidates for election as directors at our annual meeting of stockholders. To be timely, a stockholder's notice must be delivered to, or mailed and received at, our principal executive offices not less than 60 days nor more than 90 days prior to the annual meeting of stockholders. Our restated bylaws also provide advance notice procedures for stockholders to nominate candidates for election as directors at a special meeting of stockholders. To be timely, a stockholder's notice must be delivered to, or mailed and received at, our principal executive offices not later than the close of business on the tenth business day following the date on which notice of such meeting is first given to stockholders. Our restated bylaws also specify certain requirements regarding the form and content of a stockholder's notice. These provisions might preclude our stockholders from making nominations for directors at our annual and/or a special meeting of stockholders.

- Issuance of Undesignated Preferred Stock. Our board of directors has the authority, without further 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. Our board may utilize these shares for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions and employee benefits plans. The existence of authorized but unissued shares of preferred stock would enable our board 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. If we issue such shares without stockholder approval and in violation of limitations imposed by any stock exchange on which our stock may then be trading, our stock could be delisted.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer and Trust Company, LLC.

Stock Exchange Listing

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

Exhibit 10.30

LOAN AND SECURITY AGREEMENT

Dated as of November 22, 2022

between

EYENOVIA, INC.,
a Delaware corporation,

as "Borrower",

and

AVENUE CAPITAL MANAGEMENT II, L.P.,
a Delaware limited partnership,
as administrative agent and collateral agent (in such capacity "Agent")
and

AVENUE VENTURE OPPORTUNITIES FUND, L.P. II,
a Delaware limited partnership ("Avenue 2"), as a lender
and

AVENUE VENTURE OPPORTUNITIES FUND, L.P.,
a Delaware limited partnership ("Avenue"), as a lender
(together with Avenue 2, each a "Lender" and collectively, "Lenders")

LOAN AND SECURITY AGREEMENT

Borrower, Lenders and Agent have entered or anticipate entering into one or more transactions pursuant to which each Lender agrees to make available to Borrower a loan facility governed by the terms and conditions set forth in this document and one or more Supplements executed by Borrower, Lenders and Agent which incorporate this document by reference. Each Supplement constitutes a supplement to and forms part of this document, and will be read and construed as one with this document, so that this document and the Supplement constitute a single agreement between the parties (collectively referred to as this **"Agreement"**).

Accordingly, the parties agree as follows:

ARTICLE 1 - INTERPRETATION

1.1 Definitions. The terms defined in Article 10 and in the Supplement will have the meanings therein specified for purposes of this Agreement.

1.2 Inconsistency. In the event of any inconsistency between the provisions of any Supplement and this document, the provisions of the Supplement will be controlling for the purpose of all relevant transactions.

ARTICLE 2 - THE COMMITMENT AND LOANS

2.1 The Commitment. Subject to the terms and conditions of this Agreement, each Lender agrees to make term loans to Borrower from time to time from the Closing Date and to and including the Termination Date in an aggregate principal amount not exceeding the Commitment. The Commitment is not a revolving credit commitment, and Borrower does not have the right to repay and reborrow hereunder. Each Loan requested by Borrower to be made on a single Business Day shall be for a minimum principal amount set forth in the Supplement, except to the extent the remaining Commitment is a lesser amount.

2.2 Notes Evidencing Loans; Repayment. Each Loan shall be evidenced by a separate Note payable to the order of each Lender of such Loan, in the total principal amount of such Loan. Principal and interest of each Loan shall be payable at the times and in the manner set forth in the Note and regularly scheduled payments thereof shall be effected by automatic debit of the appropriate funds from Borrower's Primary Operating Account as specified in the Supplement hereto. Repayment of the Loans and payment of all other amounts owed to each Lender will be paid by Borrower in the currency in which the same has been provided (i.e., United States Dollars).

2.3 Procedures for Borrowing.

(a) At least five (5) Business Days prior to a proposed Borrowing Date (or (i) in the case of the Loan to be made on the Closing Date, no later than the Closing Date or (ii) otherwise, such lesser period of time as may be agreed upon by Agent in its sole discretion), Agent shall have received from Borrower a written request for a borrowing hereunder (a **"Borrowing Request"**). Each Borrowing Request shall be in substantially the form of Exhibit "B" to the Supplement, shall be executed by a responsible executive or financial officer of Borrower, and shall state how much is requested, and shall be accompanied by such other information and documentation as Agent may reasonably request, including the executed Note(s) for the Loan(s) covered by such Borrowing Request.

(b) No later than 1:00 p.m. Pacific Standard Time on any Borrowing Date, if Borrower has satisfied the applicable conditions precedent in Article 4 by 9:00 a.m. Pacific Standard Time on such Borrowing Date, each Lender shall make its applicable Loan available to Borrower in immediately available funds.

2.4 Interest. Except as otherwise specified in the applicable Note and/or Supplement, Basic Interest on the outstanding principal balance of each Loan shall accrue daily at the Designated Rate from the applicable Borrowing Date. If the outstanding principal balance of such Loan is not paid at maturity, interest shall accrue at the Default Rate until paid in full, as further set forth herein.

2.5 Intentionally Omitted.

2.6 Interest Rate Calculation. Basic Interest, along with charges and fees under this Agreement and any Loan Document, shall be calculated for actual days elapsed on the basis of a 360-day year, which results in higher interest, charge or fee payments than if a 365-day year were used. In no event shall Borrower be obligated to pay Agent or any Lender interest, charges

or fees at a rate in excess of the highest rate permitted by applicable law from time to time in effect.

2.7 Default Interest. Upon written notice to the Borrower (electronic mail being sufficient) by Agent or any Lender, any unpaid payments in respect of the Obligations shall bear interest from their respective maturities, whether scheduled or accelerated, at the Default Rate, compounded monthly. Borrower shall pay such interest promptly on written (electronic mail being sufficient) demand.

2.8 Late Charges. If Borrower is late in making any scheduled payment in respect of the Obligations by more than five (5) days, then Borrower agrees to pay a late charge of five percent (5%) of the payment due, but not less than Fifty Dollars ($50.00) for any one such delinquent payment. This late charge may be charged by any Lender for the purpose of defraying the expenses incidental to the handling of such delinquent amounts. Borrower acknowledges that such late charge represents a reasonable sum considering all of the circumstances existing on the date of this Agreement and represents a fair and reasonable estimate of the costs that will be sustained by such Lender due to the failure of Borrower to make timely payments. Borrower further agrees that proof of actual damages would be costly and inconvenient. Such late charge shall be paid without prejudice to the right of any Lender and Agent to collect any other amounts provided to be paid or to declare a default under this Agreement or any of the other Loan Documents or from exercising any other rights and remedies of Agent.

2.9 Lender's Records. Principal, Basic Interest and all other sums owed under any Loan Document shall be evidenced by entries in records maintained by each Lender for such purpose. Each payment on and any other credits with respect to principal, Basic Interest and all other sums outstanding under any Loan Document shall be evidenced by entries in such records. Absent manifest error, each Lender's records shall be conclusive evidence thereof.

2.10 Grant of Security Interests; Filing of Financing Statements.

(a) To secure the timely payment and performance of all of Borrower's Obligations, Borrower hereby grants to Agent, for the ratable benefit of the Lenders, continuing security interests in all of the Collateral. In connection with the foregoing, Borrower authorizes Agent to prepare and file any financing statements describing the Collateral without otherwise obtaining Borrower's signature or consent with respect to the filing of such financing statements. Such financing statements may indicate the Collateral as "all assets of the Debtor" or words of similar effect.

(b) In furtherance of Borrower's grant of the security interests in the Collateral pursuant to Section 2.10(a) above, Borrower hereby pledges and grants to Agent a security interest in all the Shares, together with all proceeds and substitutions thereof, all cash, stock and other moneys and property paid thereon, all rights to subscribe for securities declared or granted in connection therewith, and all other cash and noncash proceeds of the foregoing, as security for the performance of the Obligations. On the Closing Date or at any time thereafter following Agent's request, the certificate or certificates for the Shares constituting Collateral will be delivered to the Agent, accompanied by an instrument of assignment duly executed in blank by Borrower, unless such Shares have not been certificated. To the extent required by the terms and conditions governing the Shares, Borrower shall cause the books of each entity whose Shares are part of the Collateral and any transfer agent to reflect the pledge of the Shares. Upon the occurrence and during the continuance of an Event of Default hereunder and upon one (1) Business Day's written notice (electronic mail being sufficient) from Agent to the Borrower, Agent may effect the transfer of any securities included in the Collateral (including but not limited to the Shares) into the name of Agent and cause new certificates representing such securities to be issued in the name of Agent or its transferee(s). Borrower will execute and deliver such documents, and take or cause to be taken such actions, as Agent may reasonably request in writing (electronic mail being sufficient) to perfect or continue the perfection of Agent's security interest in the Shares. Except as provided in the following sentence, Borrower shall be entitled to exercise any voting rights with respect to the Shares and to give consents, waivers and ratifications in respect thereof, provided that no vote shall be cast, consent, waiver or ratification given or action taken which would constitute a violation of any of the terms of this Agreement. All such rights to vote and give consents, waivers and ratifications shall terminate upon the occurrence and continuance of an Event of Default and Agent's one (1) Business Day's written notice (electronic mail being sufficient) to Borrower of Agent's intent to exercise its rights and remedies on behalf of the Lenders under this Agreement, including this Section 2.10(b).

(c) Borrower is and shall remain absolutely and unconditionally liable for the performance of its Obligations, including, without limitation, any deficiency by reason of the failure of the Collateral to

satisfy all amounts due to each Lender under any of the Loan Documents.

(d) All Collateral pledged by Borrower under this Agreement and any Supplement shall secure the timely payment and performance of all Obligations. Except as expressly provided in this Agreement, no Collateral pledged under this Agreement or any Supplement shall be released until such time as all Obligations have been satisfied and paid in full (other than inchoate indemnity obligations).

ARTICLE 3 - REPRESENTATIONS AND WARRANTIES

Borrower represents and warrants that, except as set forth in any Supplement or the Schedule of Exceptions hereto, if any, as of the Closing Date and each other Borrowing Date:

3.1 Due Organization. Borrower is a corporation duly organized and validly existing in good standing under the laws of the jurisdiction of its incorporation, and is duly qualified to conduct business and is in good standing in each other jurisdiction in which its business is conducted or its properties are located, except where the failure to be so qualified would not reasonably be expected to have a Material Adverse Effect.

3.2 Authorization, Validity and Enforceability. The execution, delivery and performance of all Loan Documents executed by Borrower are within Borrower's powers, have been duly authorized, and are not in conflict with Borrower's certificate of incorporation or by-laws, or the terms of any charter or other organizational document of Borrower, as amended from time to time; and all such Loan Documents constitute valid and binding obligations of Borrower, enforceable in accordance with their terms (except as may be limited by bankruptcy, insolvency and similar laws affecting the enforcement of creditors' rights in general, and subject to general principles of equity).

3.3 Compliance with Applicable Laws. Borrower has complied with all licensing, permit and fictitious name requirements necessary to lawfully conduct the business in which it is engaged, and to any sales, leases or the furnishing of services by Borrower, including without limitation those requiring consumer or other disclosures, the noncompliance with which would have a Material Adverse Effect.

3.4 No Conflict. The execution, delivery, and performance by Borrower of all Loan Documents are not in conflict with any law, rule, regulation, order or directive, or any indenture, agreement, or undertaking to which Borrower is a party or by which Borrower may be bound or affected in any material respect. Without limiting the generality of the foregoing, the issuance of the Warrant and the grant of registration rights in connection therewith do not violate any agreement or instrument by which Borrower is bound or require the consent of any holders of Borrower's securities other than consents which have been obtained prior to the Closing Date.

3.5 No Litigation, Claims or Proceedings. There is no litigation, tax claim, proceeding or dispute pending, or, to the knowledge of Borrower, threatened against or affecting Borrower, its property or the conduct of its business except any litigation, tax claim, proceeding or dispute that could not reasonably be expected to have a Material Adverse Effect.

3.6 Correctness of Financial Statements. Borrower's financial statements which have been delivered to Lender fairly and accurately, in all material respects, reflect Borrower's financial condition in accordance with GAAP as of the latest date of such financial statements; and, since that date there has been no Material Adverse Change.

3.7 No Subsidiaries. As of the Closing Date, Borrower is not a majority owner of or in a control relationship with any other business entity.

3.8 Environmental Matters. To its knowledge after reasonable inquiry, Borrower has concluded that Borrower is in compliance with Environmental Laws, except to the extent a failure to be in such compliance would not reasonably be expected to have a Material Adverse Effect.

3.9 No Event of Default. Immediately after giving effect to this Agreement, no Default or Event of Default has occurred and is continuing.

3.10 Full Disclosure. None of the representations or warranties made by Borrower in the Loan Documents as of the date such representations and warranties are made or deemed made, and none of the written statements contained in any exhibit, report, statement or certificate furnished by or on behalf of Borrower in connection with the Loan Documents (including disclosure materials delivered by or on behalf of Borrower to Agent or any Lender prior to the Closing Date or pursuant to Section 5.2 hereof), taken as a whole, contains any untrue statement of a material fact or omits any material fact required to be stated therein or necessary to make the statements made

therein, in light of the circumstances under which they are made, not misleading as of the time when made or delivered; provided that, with respect to projected financial information, the Borrower represents only that such information was prepared in good faith based upon assumptions believed to be reasonable at the time delivered and, if such projected financial information was delivered prior to the Closing Date, as of the Closing Date (it being the understanding that the projections, by their nature, are inherently uncertain, no assurances are being given that the results reflected in the projections will be achieved, and actual results during the period or periods covered by any such projections may differ from the projected results in material respects).

3.11 Specific Representations Regarding Collateral.

(a) Title. Except for the security interests created by this Agreement and Permitted Liens, (i) Borrower is the unconditional legal and beneficial owner of the Collateral, and (ii) the Collateral is genuine and subject to no Liens other than Permitted Liens. There exist no prior assignments or encumbrances of record with the U.S. Patent and Trademark Office or U.S. Copyright Office affecting any Collateral in favor of any third party, other than Permitted Liens.

(b) Rights to Payment. The names of the obligors, amount owing to Borrower, due dates and all other information with respect to the Rights to Payment are and will be correctly stated in all material respects in all Records relating to the Rights to Payment.

(c) Location of Collateral. As of the Closing Date, Borrower's chief executive office, Inventory, Records, Equipment, and any other offices or places of business are located at the address(es) shown on the Supplement.

(d) Business Names. Other than its full corporate name, Borrower has not conducted business using any trade names or fictitious business names except as shown on the Supplement.

3.12 Copyrights, Patents, Trademarks and Licenses.

(a) Borrower owns or is licensed or otherwise has the right to use all of the patents, trademarks, service marks, trade names, copyrights, contractual franchises, authorizations and other similar rights that are reasonably necessary for the operation of its business, without known material conflict with the rights of any other Person.

(b) To Borrower's knowledge, no slogan or other advertising device, product, process, method, substance, part or other material now employed, or now contemplated to be employed, by Borrower infringes upon any rights held by any other Person in any material respect.

(c) No claim or litigation regarding any of the foregoing is pending or, to Borrower's knowledge, threatened, and, to Borrower's knowledge, no patent, invention, device, application, principle or any statute, law, rule, regulation, standard or code is pending or proposed which, in either case, could reasonably be expected to have a Material Adverse Effect.

3.13 Regulatory Compliance. Borrower has met the minimum funding requirements of ERISA with respect to any employee benefit plans subject to ERISA. No event has occurred resulting from Borrower's failure to comply with ERISA that is reasonably likely to result in Borrower's incurring any liability that could have a Material Adverse Effect. Borrower is not required to be registered as an "investment company" or a company "controlled" by an "investment company" within the meaning of the Investment Company Act of 1940. Borrower is not engaged principally, or as one of its important activities, in the business of extending credit for the purpose of purchasing or carrying margin stock (within the meaning of Regulations T and U of the Board of Governors of the Federal Reserve System). Borrower has complied in all material respects with all the provisions of the Federal Fair Labor Standards Act.

3.14 Shares. Borrower has full power and authority to create a first priority Lien on the Shares and no disability or contractual obligation exists that would prohibit Borrower from pledging the Shares pursuant to this Agreement. To Borrower's knowledge, there are no subscriptions, warrants, rights of first refusal or other restrictions on transfer relative to, or options exercisable with respect to the Shares. The Shares have been and will be duly authorized and validly issued, and are fully paid and non-assessable. To Borrower's knowledge, the Shares are not the subject of any present or threatened suit, action, arbitration, administrative or other proceeding, and, to Borrower's knowledge, no reasonable grounds for the institution of any such proceedings exist.

3.15 Compliance with Anti-Corruption Laws. Borrower has not taken any action that would cause a violation of any anti-corruption law, including but not

limited to, the Foreign Corrupt Practices Act, the United Kingdom Bribery Act, and all other applicable anti-corruption laws. Borrower, its employees, agents and representatives have not, directly or indirectly, offered, paid, given, promised or authorized the payment of any money, gift or anything of value to any person acting in an official capacity for any government department, agency or instrumentality, including state-owned or controlled companies or entities, and public international organizations, as well as a political party or official thereof or candidate for political office. None of Borrower's principals or staff are officers, employees or representatives of governments, government agencies, or government-owned or controlled enterprises.

3.16 Survival. The representations and warranties of Borrower as set forth in this Agreement survive the execution and delivery of this Agreement.

ARTICLE 4 - CONDITIONS PRECEDENT

4.1 Conditions to First Loan. The obligation of each Lender to make its first Loan hereunder is, in addition to the conditions precedent specified in Section 4.2 and in any Supplement, subject to the fulfillment of the following conditions and to the receipt by Agent of the documents described below, duly executed and in form and substance satisfactory to Agent and its counsel:

(a) Resolutions. A certified copy of the resolutions of the Board of Directors of Borrower authorizing the execution, delivery and performance by Borrower of the Loan Documents.

(b) Incumbency and Signatures. A certificate of the secretary of Borrower certifying the names of the officer or officers of Borrower authorized to sign the Loan Documents, together with a sample of the true signature of each such officer.

(c) Legal Opinion. The opinion of legal counsel for Borrower as to such matters as Agent may reasonably request, in form and substance reasonably satisfactory to Agent.

(d) Charter Documents. Copies of the organizational and charter documents of Borrower (e.g., Articles or Certificate of Incorporation and Bylaws), as amended through the Closing Date, certified by an officer of Borrower as being true, correct and complete.

(e) This Agreement. Counterparts of this Agreement and the initial Supplement, with all schedules completed and attached thereto, and disclosing such information as is acceptable to Agent.

(f) Financing Statements. Filing copies (or other evidence of filing satisfactory to Agent and its counsel) of such UCC financing statements, collateral assignments, account control agreements, and termination statements, with respect to the Collateral as Agent shall reasonably request.

(g) Intellectual Property Security Agreement. An Intellectual Property Security Agreement executed by Borrower in form and substance satisfactory to Agent.

(h) Lien Searches. UCC lien, judgment, bankruptcy and tax lien searches of Borrower from such jurisdictions or offices as Agent r may reasonably request, all as of a date reasonably satisfactory to Agent and its counsel.

(i) Good Standing Certificate. A certificate of status or good standing of Borrower as of a date reasonably acceptable to Agent from the jurisdiction of Borrower's organization and any foreign jurisdictions where Borrower is qualified to do business, except any foreign jurisdictions where the failure to be so qualified could not reasonably be expected to have a Material Adverse Effect.

(j) Equity Grant. The grant of equity by Borrower is exercisable for such number, type and class of shares of Borrower's capital stock, and for an initial exercise price as is specified in the documents governing such grant.

(k) Insurance Certificates. Insurance certificates showing Agent as loss payee or additional insured.

(l) VISION -2. Receipt by Agent of evidence, as determined by Agent in its reasonable discretion, that Borrower has received positive phase 3 VISION-2 clinical trial data.

(m) Mydcombi. Receipt by Agent of evidence, as determined by Agent in its reasonable discretion, that Borrower has submitted the Mydcombi NDA for review by the FDA.

(n) Other Documents. Such other documents and instruments as Agent may reasonably request to effectuate the intents and purposes of this Agreement.

4.2 Conditions to All Loans. The obligation of each Lender to make each Loan is subject to the following further conditions precedent that:

(a) No Default. No Default or Event of Default has occurred and is continuing or will immediately result from the making of such Loan, and the representations and warranties of Borrower contained in Article 3 of this Agreement and Part 3 of each Supplement are true and correct in all material respects as of the Borrowing Date of such Loan.

(b) No Material Adverse Change. Since the date of Borrower's most recent financial statements, no event has occurred that has had or could reasonably be expected to have a Material Adverse Change.

(c) Borrowing Request. Borrower shall have delivered to Agent a Borrowing Request for such Loan.

(d) Note. Borrower shall have delivered an executed Note evidencing such Loan, substantially in the form attached to the Supplement as an exhibit.

(e) Supplemental Lien Filings. Borrower shall have executed and delivered such amendments or supplements to this Agreement and additional Security Documents, financing statements and third party waivers as Agent may reasonably request in connection with such Loan, in order to create, protect or perfect or to maintain the perfection of Agent's Liens on the Collateral.

(f) VCOC Limitation. Lender shall not be obligated to make any Loan under its Commitment if at the time of or after giving effect to the proposed Loan Lender would no longer qualify as: (i) a "venture capital operating company" under U.S. Department of Labor Regulations Section 2510.3-101(d), Title 29 of the Code of Federal Regulations, as amended; and (ii) a "business development company" under the provisions of federal Investment Company Act of 1940, as amended; and (iii) a "regulated investment company" under the provisions of the Internal Revenue Code of 1986, as amended.

(g) Financial Projections. Borrower shall have delivered to Agent Borrower's business plan and/or financial projections or forecasts as most recently approved by Borrower's Board of Directors.

4.3 Post-Closing Conditions. Borrower shall use commercially reasonable efforts to deliver the items set forth below within the timeframe permitted (or by such other date as Agent may approve in writing), in each case, in form and substance reasonably acceptable to Agent.

(a) Landlord Waiver. Within thirty (30) days of the Closing Date, a Waiver from each landlord of any leased location where Borrower maintains Collateral valued in excess of One Hundred Thousand Dollars ($100,000), in accordance with Section 5.9(e) hereof.

(b) Bailee Waiver. Within thirty (30) days of the Closing Date, a Waiver from each bailee with which Borrower maintains Collateral valued in excess of One Hundred Thousand Dollars ($100,000), in accordance with Section 5.9(e) hereof.

ARTICLE 5 - AFFIRMATIVE COVENANTS

During the term of this Agreement and until its performance of all Obligations (other than inchoate indemnity obligations), Borrower will:

5.1 Notice to Agent. Promptly give written notice to Agent of:

(a) Any litigation or administrative or regulatory proceeding affecting Borrower where the amount claimed against Borrower is at the Threshold Amount or more, or where the granting of the relief requested could reasonably be expected to have a Material Adverse Effect; or of the acquisition by Borrower of any commercial tort claim, including brief details of such claim and such other information as Agent may reasonably request to enable Agent to better perfect its Lien in such commercial tort claim as Collateral.

(b) Any substantial dispute which may exist between Borrower and any governmental or regulatory authority that could reasonably be expected to have a Material Adverse Effect.

(c) The occurrence of any Default or any Event of Default.

(d) Any change in the location of any of Borrower's places of business or Collateral (other than Collateral out for repair, in the possession of employees or in transit), or of the establishment of any new, or the discontinuance of any existing, place of business.

(e) Any dispute or default by Borrower or any other party under any joint venture, partnering, distribution, cross-licensing, strategic alliance, collaborative research or manufacturing, license or

similar agreement which could reasonably be expected to have a Material Adverse Effect.

(f) Any other matter which has resulted or might reasonably result in a Material Adverse Change.

(g) Any Subsidiary Borrower intends to acquire or create.

5.2 Financial Statements. Deliver to Agent or cause to be delivered to Agent, in form and detail reasonably satisfactory to Agent the following financial and other information, which Borrower warrants shall be accurate and complete in all material respects:

(a) Monthly Financial Statements. As soon as available but no later than thirty (30) days after the end of each month, Borrower's unaudited balance sheet as of the end of such period, and Borrower's unaudited income statement and cash flow statement for such period and for that portion of Borrower's financial reporting year ending with such period, prepared in accordance with GAAP and attested by a responsible financial officer of Borrower as being complete and correct in all material respects and fairly presenting Borrower's financial condition and the results of Borrower's operations as of the date(s) and for the period(s) covered thereby.

(b) Quarterly Financial Statements. As soon as available but no later than forty-five (45) days after the end of each financial reporting quarter, Borrower's unaudited balance sheet as of the end of such period, and Borrower's unaudited income statement and cash flow statement for such period and for that portion of Borrower's financial reporting year ending with such period, prepared in accordance with GAAP and attested by a responsible financial officer of Borrower as being complete and correct in all material respects and fairly presenting Borrower's financial condition and the results of Borrower's operations as of the date(s) and for the period(s) covered thereby, subject to normal year-end audit adjustments (which financial statements, for the avoidance of doubt, shall be deemed to be delivered in accordance with this clause (b) when and to the extent such financial statements are filed by Borrower with the SEC).

(c) Year-End Financial Statements. As soon as available but no later than one hundred eighty (180) days after the end of each financial reporting year, a complete copy of Borrower's audit report, which shall include balance sheet, income statement, statement of changes in equity and statement of cash flows for such year, prepared in accordance with GAAP and certified by an independent certified public accountant selected by Borrower and reasonably satisfactory to Agent (the **"Accountant"**) (which financial statements, for the avoidance of doubt, shall be deemed to be delivered in accordance with this clause (c) when and to the extent such financial statements are filed by Borrower with the SEC). The Accountant's certification shall not be qualified or limited, in each case, due to a restricted or limited examination by the Accountant of any material portion of Borrower's records. Notwithstanding the foregoing, if Borrower's Board of Directors does not require Borrower's financial statements to be audited for a particular reporting year, then Borrower shall deliver to Agent unaudited financial statements for such year, including the items described in, and in the timeframe specified in, this Section 5.2(b) (other than the Accountant's certification).

(d) Compliance Certificates. Simultaneously with the delivery of each set of financial statements referred to in paragraphs (a) and (b) above, a certificate of the chief financial officer of Borrower (or other executive officer) substantially in the form of Exhibit "C" to the Supplement (a **"Compliance Certificate"**) stating, among other things, whether any Default or Event of Default exists on the date of such certificate, and if so, setting forth the details thereof and the action which Borrower is taking or proposes to take with respect thereto.

(e) Government Required Reports. Promptly after sending, issuing, making available, or filing, copies of all material reports, proxy statements, and financial statements that Borrower sends or makes available generally to its stockholders, and, not later than five (5) days after actual filing or the date such filing was first due, all registration statements and reports that Borrower files or is required to file with the Securities and Exchange Commission, or any other governmental or regulatory authority having similar authority (which copies, for the avoidance of doubt, shall be deemed to be delivered in accordance with this clause (e) when and to the extent such underlying financial statements, proxy statements or reports are filed by Borrower with the SEC and made publicly available).

(f) Other Information. Such other statements, lists of property and accounts, budgets (as updated), sales projections, forecasts, reports, 409A valuation reports (as updated), operating plans, financial exhibits, capitalization tables (as updated) and information relating to equity and debt financings consummated after the Closing Date (including post-closing capitalization table(s)), or other information as Agent may from time to time reasonably request in writing (which statements or other information, for the

avoidance of doubt, shall be deemed to be delivered in accordance with this clause (f) when and to the extent such statements or other information are filed by Borrower with the SEC).

(g) Board Packages. In addition to the information described in Section 5.2(e), Borrower will promptly provide Agent with copies of all notices, minutes, consents and other materials, financial or otherwise, which Borrower provides to its Board of Directors (collectively, **"Board Packages"**); provided, however, that Borrower need not provide Agent with copies of routine Board actions, such as option and stock grants under Borrower's equity incentive plan in the normal course of business; and provided, further, however, that such Board Packages may be redacted to the extent that (i) based on the advice of counsel, Borrower determines such redaction is reasonably necessary to preserve the attorney-client privilege, to protect highly confidential proprietary information, or for other similar reasons or (ii) such redacted material relates to Agent or any Lender (or Borrower's strategy regarding the Loans, Agent or any Lender).

5.3 [Reserved].

5.4 Existence. Maintain and preserve Borrower's existence, present form of business (including lines of business that are similar, related or incidental thereto and reasonable extensions thereof), and all rights and privileges necessary in the normal course of its business; and keep all Borrower's property in good working order and condition, ordinary wear and tear excepted, in each case, except to the extent not prohibited hereby; provided further, that Borrower shall not be required to preserve any such rights if no longer desirable in the conduct of its business.

5.5 Insurance. Obtain and keep in force insurance in such amounts and types as is usual in the type of business conducted by Borrower, with insurance carriers having a policyholder rating of not less than "A" and financial category rating of Class VII in "Best's Insurance Guide," unless otherwise approved by Agent. Such insurance policies must be in form and substance reasonably satisfactory to Agent, and shall list Agent as an additional insured or loss payee, as applicable, on endorsement(s) in form reasonably acceptable to Agent within thirty (30) days following the Closing Date. Borrower shall furnish to Agent such endorsements, and upon Agent's request, copies of any or all such policies.

5.6 Accounting Records. Maintain adequate books, accounts and records, and prepare all financial statements in accordance with GAAP, and in compliance with the regulations of any governmental or regulatory authority having jurisdiction over Borrower or Borrower's business; and permit employees or agents of Agent during normal business hours on reasonable advance written notice (no less than two (2) Business Days) as Agent may request, at Borrower's expense (not more than once per 12-month period unless an Event of Default has occurred and is continuing), to inspect Borrower's properties, and to examine, review and audit, and make copies and memoranda of Borrower's books, accounts and records; provided, however, that such books, accounts and records may be redacted to the extent that (i) based on the advice of counsel, Borrower determines such redaction is reasonably necessary to preserve the attorney-client privilege, to protect highly confidential proprietary information, or for other similar reasons or (ii) such redacted material relates to Agent or any Lender (or Borrower's strategy regarding the Loans, Agent or any Lender).

5.7 Compliance with Laws. Comply with all laws (including Environmental Laws), rules, regulations applicable to, and all orders and directives of any governmental or regulatory authority having jurisdiction over, Borrower or Borrower's business, and with all material agreements to which Borrower is a party, except where the failure to so comply would not have a Material Adverse Effect.

5.8 Taxes and Other Liabilities. Pay all Borrower's Indebtedness when due; pay all taxes and other governmental or regulatory assessments before delinquency or before any penalty attaches thereto, except as may be contested in good faith by the appropriate procedures and for which Borrower shall maintain appropriate reserves; and timely file all required tax returns (subject to any applicable extensions).

5.9 Special Collateral Covenants.

(a) Maintenance of Collateral; Inspection. Do all things reasonably necessary to maintain, preserve, protect and keep all Collateral in good working order and salable condition, ordinary wear and tear excepted, deal with the Collateral in all commercially reasonable ways as are considered good practice by owners of like property, and use the Collateral lawfully and, to the extent applicable, only as permitted by Borrower's insurance policies, subject to Transfers permitted by Section 6.5. Maintain, or cause to be maintained, complete and accurate Records, in all material respects, relating to the Collateral. Upon reasonable prior written notice (no less than two (2) Business Days and electronic mail being sufficient) at

reasonable times during normal business hours (not more than once per 12-month period unless an Event of Default has occurred and is continuing), Borrower hereby authorizes Agent and each Lender's officers, employees, representatives and agents to inspect the Collateral and to discuss the Collateral and the Records relating thereto with Borrower's officers and employees, and, in the case of any Right to Payment, after consultation with Borrower, with any Person which is or may be obligated thereon; provided, however, that such Records and other related materials may be redacted to the extent that (i) based on the advice of counsel, Borrower determines such redaction is reasonably necessary to preserve the attorney-client privilege, to protect highly confidential proprietary information, or for other similar reasons or (ii) such redacted material relates to Agent or any Lender (or Borrower's strategy regarding the Loans, Agent or any Lender).

(b) Documents of Title. Not sign or authorize the signing of any financing statement or other document naming Borrower as debtor or obligor, or acquiesce or cooperate in the issuance of any bill of lading, warehouse receipt or other document or instrument of title with respect to any Collateral, except those negotiated to Lenders, or those naming Agent on behalf of the Lenders or Lenders as secured party, or if solely to create, perfect or maintain a Permitted Lien.

(c) Change in Location or Name. Without at least ten (10) days' prior written notice to Agent: (a) not relocate any Collateral or Records, its chief executive office, or establish a place of business at a location other than as specified in the Supplement; and (b) not change its name, mailing address, location of Collateral (other than Collateral out for repair, in the possession of employees or in transit), jurisdiction of incorporation or its legal structure.

(d) [Reserved].

(e) Agreement with Persons in Possession of Collateral. Use its commercially reasonable efforts to obtain and maintain such acknowledgments, consents, waivers and agreements (each a **"Waiver"**) from the owner, operator, lienholder, mortgagee, landlord or any Person in possession of tangible Collateral in excess of One Hundred Thousand Dollars ($100,000) per location as Agent may require, all in form and substance reasonably satisfactory to Agent. In addition, Agent shall have the right to require Borrower to use its commercially reasonable efforts to provide Agent with a Waiver for any Collateral that is located in a jurisdiction that provides for statutory landlord's Liens and for any location at which the Person in possession of such Collateral has a Lien thereon. Notwithstanding anything to the contrary in this Section 5.9(e), Borrower and Agent acknowledge and agree that all material Intellectual Property and Records that are maintained on items of Collateral for which Borrower is unable to provide a Waiver also shall be maintained or backed up in a manner sufficient that Agent and Lenders shall be able to have access to such Intellectual Property and Records in accordance with the exercise of Lenders' rights hereunder.

(f) Certain Agreements on Rights to Payment. Other than in the ordinary course of business, not make any material discount, credit, rebate or other reduction in the original amount owing on a Right to Payment or accept in satisfaction of a Right to Payment less than the original amount thereof.

5.10 Authorization for Automated Clearinghouse Funds Transfer. (i) Authorize Agent to initiate debit entries to Borrower's Primary Operating Account, specified in the Supplement hereto, through Automated Clearinghouse (**"ACH"**) transfers, in order to satisfy the regularly scheduled payments of principal and interest; (ii) provide Agent at least fifteen (15) days' notice of any change in Borrower's Primary Operating Account; and (iii) grant Agent any additional authorizations necessary to begin ACH debits from a new account which becomes the Primary Operating Account.

5.11 Anti-Corruption Laws. Provide true, accurate and complete information, in all material respects, in all product orders, reimbursement requests and other communications relating to Borrower and its products.

ARTICLE 6 - NEGATIVE COVENANTS

During the term of this Agreement and until the performance of all Obligations (other than inchoate indemnity obligations), Borrower will not:

6.1 Indebtedness. Be indebted for borrowed money, the deferred purchase price of property, or leases which would be capitalized in accordance with GAAP; or become liable as a surety, guarantor, accommodation party or otherwise for or upon the obligation of any other Person, except for Permitted Indebtedness.

6.2 Liens. Create, incur, assume or permit to exist any Lien, or grant any other Person a negative pledge, on any of Borrower's property, except Permitted Liens and any negative pledge in respect of any asset subject to a Lien permitted by clause (c) of

the definition of Permitted Liens. Borrower, Agent and each Lender agree that this covenant is not intended to constitute a lien, deed of trust, equitable mortgage, or security interest of any kind on any of Borrower's real property, and this Agreement shall not be recorded or recordable. Notwithstanding the foregoing, however, violation of this covenant by Borrower shall constitute an Event of Default.

6.3 Dividends. Pay any dividends or purchase, redeem or otherwise acquire or make any other distribution with respect to any of Borrower's capital stock, except (a) dividends or other distributions solely of capital stock of Borrower, (b) so long as no Event of Default has occurred and is continuing, repurchases of stock from employees or contractors upon termination of employment or services under reverse vesting or similar repurchase plans not to exceed One Hundred Thousand Dollars ($100,000) in any calendar year, (c) the conversion of Borrower's convertible securities into other securities pursuant to the terms of such convertible securities or otherwise in exchange thereof, (d) the purchase, redemption or other acquisition of shares of Borrower's capital stock with the proceeds received from a substantially concurrent issue of new shares of its capital stock and (e) not exceeding One Hundred Thousand Dollars ($100,000) during any fiscal year, pursuant to and in accordance with stock option plans or other benefit plans for management or employees of Borrower.

6.4 Fundamental Changes. (a) Liquidate or dissolve; (b) enter into, or permit any of Borrower's Subsidiaries to enter into, any Change of Control; or (c) acquire, or permit any of Borrower's Subsidiaries to acquire, all or substantially all of the capital stock or property of another Person, in each case, without the consent of Agent. Notwithstanding anything to the contrary in this Section 6.4, Borrower may enter into a transaction that will constitute a Change of Control so long as: (i) the Person that results from such Change of Control (the **"Surviving Entity"**) shall have executed and delivered to Agent an agreement in form and substance reasonably satisfactory to Agent, containing an assumption by the Surviving Entity of the due and punctual payment and performance of all Obligations and performance and observance of each covenant and condition of Borrower in the Loan Documents; (ii) all such obligations of the Surviving Entity to Lenders shall be guaranteed by any Person that directly or indirectly owns or controls 50% or more of the voting stock of the Surviving Entity; (iii) immediately after giving effect to such Change of Control, no Event of Default or, event which with the lapse of time or giving of notice or both, would result in an Event of Default shall have occurred and be continuing; and (iv) the credit risk to Lenders, in their sole discretion, with respect to the Obligations and the Collateral shall not be increased. In determining whether the proposed Change of Control would result in an increased credit risk, Lenders may consider, among other things, changes in Borrower's management team, employee base, access to equity markets, venture capital support, financial position and/or disposition of intellectual property rights which may reasonably be anticipated as a result of the Change of Control. In addition, (i) a Subsidiary may merge or consolidate into another Subsidiary and (ii) Borrower may consolidate or merge with any of Borrower's Subsidiaries provided that Borrower is the continuing or surviving Person.

6.5 Sales of Assets. Sell, transfer, lease, license or otherwise dispose of (a **"Transfer"**) any of Borrower's assets except (i) non-exclusive licenses of Intellectual Property in the ordinary course of business consistent with industry practice, provided that such licenses of Intellectual Property do not result in a legal transfer of title of the licensed Intellectual Property; provided that such licenses may be exclusive in respects other than territory; (ii) Transfers of worn-out, obsolete or surplus property, including the abandonment or lapse of Intellectual Property (each as determined by Borrower in its reasonable business judgment); (iii) Transfers of Inventory in the ordinary course of business; (iv) Transfers constituting Permitted Liens; (v) Transfers permitted in Section 6.3, 6.4, 6.6 or 6.7 hereunder; (v) Transfers of Accounts in connection with the compromise, settlement or collection thereof; (vi) Transfers of cash equivalents in the ordinary course of business; (vii) Transfers resulting from any casualty or other insured damage to, or any taking under power of eminent domain or by condemnation or similar proceeding of, any property or asset of Borrower or any Subsidiary; (viii) leases, subleases, licenses or sublicenses of real or personal property (including Intellectual Property) in the ordinary course of business and consistent with past practice; (ix) sales, transfers and other Transfers of property to the extent that (x) such property is exchanged for credit equivalent to fair market value against the purchase price of similar replacement property, or (y) the proceeds of such Transfer are promptly applied to the purchase price of such replacement property and (x) Transfers of assets (other than Intellectual Property) for fair consideration and in the ordinary course of its business.

6.6 Loans/Investments. Make or suffer to exist any loans, guaranties, advances, or investments (**"Investments"**), except for Permitted Investments.

6.7 Transactions with Related Persons. Directly or indirectly enter into any transaction with or for the benefit of a Related Person on terms more favorable to the Related Person than would have been obtainable in an "arms' length" dealing, except (a)(i) sales of equity securities by Borrower and (ii) incurrence of Subordinated Debt for capital raising purposes, on terms reasonably acceptable to Lenders (such acceptance not to be unreasonably withheld or delayed) (b) Permitted Investments, (c) dividends permitted by Section 6.3, (d) the payment of reasonable fees to directors of Borrower or any of its Subsidiaries who are not employees thereof and compensation and employee benefit arrangements paid to directors, officers or employees of Borrower in the ordinary course of business and consistent with past practice, (e) customary indemnities provided to, and reasonable and customary fees paid to, members of the board of directors of Borrower or any of its Subsidiaries; and (f) customary employment, compensation and severance arrangements for officers and other employees of Borrower or any of its Subsidiaries entered into in the ordinary course of business.

6.8 Other Business. Engage in any material line of business other than the business Borrower conducts as of the Closing Date and any business substantially similar or related or incidental thereto and reasonable extensions thereof.

6.9 Financing Statements and Other Actions. Fail to execute and deliver to Agent all financing statements, notices and other documents (including, without limitation, any filings with the United States Patent and Trademark Office and the United States Copyright Office) from time to time reasonably requested by Agent in writing (electronic mail being sufficient) to maintain a perfected first priority security interest in the Collateral in favor of Agent subject to Permitted Liens; perform such other acts, and execute and deliver to Agent such additional conveyances, assignments, agreements and instruments, as Agent may at any time reasonably request in writing (electronic mail being sufficient) in connection with the administration and enforcement of this Agreement or Agent's rights, powers and remedies hereunder.

6.10 Compliance. Become required to be registered as an "investment company" or controlled by an "investment company," within the meaning of the Investment Company Act of 1940, or become principally engaged in, or undertake as one of its important activities, the business of extending credit for the purpose of purchasing or carrying margin stock, or use the proceeds of any Loan for such purpose. Fail to meet the minimum funding requirements of ERISA, permit a Reportable Event or Prohibited Transaction, as defined in ERISA, to occur, fail to comply with the Federal Fair Labor Standards Act or violate any law or regulation, which violation could reasonably be expected to have a Material Adverse Effect or a material adverse effect on the Collateral or the priority of Agent's Lien on the Collateral, or permit any of its Subsidiaries to do any of the foregoing.

6.11 Other Deposit and Securities Accounts. Maintain any Deposit Accounts or accounts holding securities owned by Borrower except (i) Deposit Accounts and investment/securities accounts as set forth in the Supplement, and (ii) other Deposit Accounts and securities/investment accounts, in each case, with respect to which Borrower and Agent shall have taken such action as Agent reasonably deems necessary to obtain a perfected first priority security interest therein, subject to Permitted Liens. The provisions of the previous sentence shall not apply to Deposit Accounts exclusively used for payroll, payroll taxes and other employee wage and benefit payments to or for the benefit of Borrower's employees and accounts held for the benefit of third parties and identified to Agent as such.

6.12 Prepayment of Indebtedness. Prepay, redeem or otherwise satisfy in any manner prior to the scheduled repayment thereof any Indebtedness (other than the Loans and Indebtedness permitted by Section 6.1 hereof). Notwithstanding the foregoing, Agent and each Lender agrees that (a) the conversion or exchange into Borrower's equity securities of any Indebtedness (other than the Loans), (b) payment of regularly scheduled interest and principal payments as and when due in respect of any Permitted Indebtedness, other than payments in respect of any Subordinated Indebtedness which are governed by Section 6.13, (c) refinancings of Indebtedness to the extent permitted by clause (o) of the definition of Permitted Indebtedness, and (d) payment of secured Indebtedness that becomes due as a result of any Transfer of the property or assets securing such Indebtedness, in each case, shall not be prohibited by this Section 6.12.

6.13 Repayment of Subordinated Debt. Repay, prepay, redeem or otherwise satisfy in any manner any Subordinated Debt, except in accordance with the terms of any subordination agreement among Borrower, Agent and the holder(s) of such Subordinated Debt. Notwithstanding the foregoing, Agent and each Lender agree that the conversion or exchange into Borrower's equity securities of any Subordinated Debt and the payment of cash in lieu of fractional shares shall not be prohibited by this Section 6.13.

6.14 Subsidiaries.

(a) Acquire or create any Subsidiary, unless such Subsidiary becomes, at Agent and each Lender's option, either a co-borrower hereunder or executes and delivers to Agent one or more agreements, in form and substance reasonably satisfactory to Agent, containing a guaranty of the Obligations that is secured by first priority Liens on such Person's assets, subject to Permitted Liens. For clarity, the parties acknowledge and agree that Agent shall have the exclusive right to determine whether any such Person will be made a co-borrower hereunder or a guarantor of the Obligations. Prior to the acquisition or creation of any such Subsidiary, Borrower shall notify Agent thereof in writing, which notice shall contain the jurisdiction of such Person's formation and include a description of such Person's fully diluted capitalization and Borrower's purpose for its acquisition or creation of such Subsidiary.

(b) Sell, transfer, encumber or otherwise dispose of Borrower's ownership interest in any Subsidiary other than Permitted Liens and Transfers permitted pursuant to Section 6.5.

(c) Cause or permit a Subsidiary to do any of the following: (i) grant Liens on such Subsidiary's assets, except for (x) Liens that would constitute Permitted Liens if incurred by Borrower and (y) Liens on any property held or acquired by such Subsidiary in the ordinary course of its business securing Indebtedness incurred or assumed for the purpose of financing all or any part of the cost of acquiring such property; provided, that, in the case of the foregoing clause (y), such Lien attaches solely to the property acquired with such Indebtedness and that the principal amount of such Indebtedness does not exceed one hundred percent (100%) of the cost of such property; and (ii) issue any additional Shares, except to Borrower or a wholly owned Subsidiary of Borrower.

6.15 Leases. Create, incur, assume, or suffer to exist any obligation as lessee for the rental or hire of any personal property ("**Personal Property Leases**"), except for Personal Property Leases of Equipment in the ordinary course of business that do not in the aggregate require Borrower to make payments (including taxes, insurance, maintenance and similar expenses which Borrower is required to pay under the terms of any such lease) in any calendar year in excess of One Hundred Thousand Dollars ($100,000) in aggregate amount. For the avoidance of doubt, this Section 6.15 will not be applicable to Indebtedness otherwise permitted under Section 6.1(f) of this Agreement.

6.16 Anti-Corruption Laws.

(a) Take any action that would cause a violation of any anti-corruption law, including but not limited to, the Foreign Corrupt Practices Act, the United Kingdom Bribery Act, and all other applicable anti-corruption laws.

(b) Directly or indirectly, offer, pay, give, promise or authorize the payment of any money, gift, or anything of value to any person acting in an official capacity for any government department, agency, or instrumentality, including state-owned or controlled companies or entities, and public international organizations, as well as a political party or official thereof or candidates for political office, except in compliance with applicable law.

ARTICLE 7 - EVENTS OF DEFAULT

7.1 Events of Default; Acceleration. Upon the occurrence and during the continuation of any Event of Default, the obligation of Lender to make any additional Loan shall be suspended. The occurrence and continuation of any of the following (each, an **"Event of Default"**) shall at the option of Agent at the direction of Lenders (1) make all sums of Basic Interest and principal, as well as any other Obligations and amounts owing under any Loan Documents, immediately due and payable without notice of default, presentment or demand for payment, protest or notice of nonpayment or dishonor or any other notices or demands, and (2) give Agent the right to exercise any other right or remedy provided by contract or applicable law:

(a) Borrower shall fail to pay any principal or interest under this Agreement or any Note, or fail to pay any fees or other charges when due under any Loan Document, and such failure continues for three (3) Business Days or more after the same first becomes due; or an Event of Default as defined in any other Loan Document shall have occurred.

(b) Any representation or warranty made, or financial statement, certificate or other document provided, by Borrower under any Loan Document shall prove to have been false or misleading in any material respect when made or deemed made herein.

(c) If there occurs any circumstance or circumstances that could reasonably be expected to have a Material Adverse Effect.

(d) (i) Borrower shall fail to pay its debts generally as they become due; or (ii) Borrower shall

commence any Insolvency Proceeding with respect to itself, an involuntary Insolvency Proceeding shall be filed against Borrower, or a custodian, receiver, trustee, assignee for the benefit of creditors, or other similar official, shall be appointed to take possession, custody or control of the properties of Borrower, and such involuntary Insolvency Proceeding, petition or appointment is acquiesced to by Borrower or is not dismissed within forty five (45) days; or (iii) the dissolution, winding up, or termination of the business or cessation of operations of Borrower (including any transaction or series of related transactions deemed to be a liquidation, dissolution or winding up of Borrower pursuant to the provisions of Borrower's charter documents); or (iv) Borrower shall take any corporate action for the purpose of effecting, approving, or consenting to any of the foregoing.

(e) Borrower shall be in default beyond any applicable period of grace or cure under any other agreement involving Indebtedness owed to any Person in an amount in excess of the Threshold Amount (i) resulting in a right by any Person to accelerate or cause such Indebtedness to become due prior to its scheduled maturity or (ii) that enables or permits (with or without the giving of notice, the lapse of time or both) the holder or holders of such Indebtedness or any trustee or agent on its or their behalf to cause such Indebtedness to become due, or to require the prepayment, repurchase, redemption or defeasance thereof, prior to its scheduled maturity.

(f) Any governmental or regulatory authority shall take any judicial or administrative action, or any defined benefit pension plan maintained by Borrower shall have any unfunded liabilities, any of which, in the reasonable judgment of Agent and each Lender, could reasonably be expected to have a Material Adverse Effect.

(g) Any sale, transfer or other disposition of all or a substantial or material part of the assets of Borrower, including without limitation to any trust or similar entity, shall occur.

(h) Any judgment(s) singly or in the aggregate in excess of the Threshold Amount shall be entered against Borrower which remain unsatisfied, unvacated or unstayed pending appeal for thirty (30) or more days after entry thereof (to the extent not covered by independent third-party insurance as to which the insurer does not dispute coverage).

(i) Borrower shall fail to perform or observe any covenant contained in Article 6 of this Agreement.

(j) Borrower shall fail to perform or observe any covenant contained in Article 5 or elsewhere in this Agreement or any other Loan Document (other than a covenant which is dealt with specifically elsewhere in this Article 7) and, if capable of being cured, the breach of such covenant is not cured within ten (10) Business Days after the sooner to occur of Borrower's receipt of notice of such breach from Agent or the date on which such breach first becomes known to any officer of Borrower (the "**Notice Date**"); provided, however that if such breach is not capable of being cured within such 10-Business Day period and Borrower timely notifies Agent of such fact and Borrower diligently pursues such cure, then the cure period shall be extended to the date requested in Borrower's notice but in no event more than thirty (30) Business Days from the Notice Date.

7.2 Remedies upon Default. Upon the occurrence and during the continuance of an Event of Default, Agent, at the direction of Lenders, shall be entitled to, at its option, exercise any or all of the rights and remedies available to a secured party under the UCC or any other applicable law, and exercise any or all of its rights and remedies provided for in this Agreement and in any other Loan Document. The obligations of Borrower under this Agreement shall continue to be effective or be reinstated, as the case may be, if at any time any payment of any Obligations is rescinded or must otherwise be returned by Agent or any Lender upon, on account of, or in connection with, the insolvency, bankruptcy or reorganization of Borrower or otherwise, all as though such payment had not been made.

7.3 Sale of Collateral. Upon the occurrence and during the continuance of an Event of Default and upon prior written notice (electronic mail being sufficient) by Agent to Borrower, Agent may sell all or any part of the Collateral, at public or private sales, to itself, a wholesaler, retailer or investor, for cash, upon credit or for future delivery, and at such price or prices as Agent may, at the direction of Lenders, deem commercially reasonable. To the extent permitted by law, Borrower hereby specifically waives all rights of redemption and any rights of stay or appraisal which it has or may have under any applicable law in effect from time to time. Any such public or private sales shall be held at such times and at such place(s) as Agent, at the direction of Lenders, may determine. In case of the sale of all or any part of the Collateral on credit or for future delivery, the Collateral so sold may be retained by Agent on behalf of the Lenders until the selling price is paid by the purchaser, but Agent shall not incur any liability in case of the failure of such purchaser to pay for the Collateral and, in case of any such failure, such

Collateral may be resold. Agent may, at the direction of Lenders, instead of exercising its power of sale, proceed to enforce its security interest in the Collateral by seeking a judgment or decree of a court of competent jurisdiction. Without limiting the generality of the foregoing, if an Event of Default is in existence,

(1) Subject to the rights of any third parties, Agent may license, or sublicense, whether general, special or otherwise, and whether on an exclusive or non-exclusive basis, any Copyrights, Patents or Trademarks included in the Collateral throughout the world for such term or terms, on such conditions and in such manner as Lenders shall in their sole discretion determine;

(2) Agent may (without assuming any obligations or liability thereunder), at any time and from time to time, enforce (and shall have the exclusive right to enforce) against any licensee or sublicensee all rights and remedies of Borrower in, to and under any Copyright Licenses, Patent Licenses or Trademark Licenses and take or refrain from taking any action under any thereof, and Borrower hereby releases Agent and each Lender from, and agrees to hold Agent and each Lender free and harmless from and against any claims arising out of, any lawful action so taken or omitted to be taken with respect thereto other than claims arising out of Agent's or any Lender's gross negligence or willful misconduct; and

(3) Upon request by Agent, Borrower will execute and deliver to Agent a power of attorney, in form and substance reasonably satisfactory to Agent for the implementation of any lease, assignment, license, sublicense, grant of option, sale or other disposition of a Copyright, Patent or Trademark. In the event of any such disposition pursuant to this clause 3, Borrower shall supply its know-how and expertise relating to the products or services made or rendered in connection with Patents, the manufacture and sale of the products bearing Trademarks, and its customer lists and other records relating to such Copyrights, Patents or Trademarks and to the distribution of said products, to Agent.

(4) If, at any time when Agent or Lenders shall determine to exercise the right to sell the whole or any part of the Shares hereunder, such Shares or the part thereof to be sold shall not, for any reason whatsoever, be effectively registered under the Securities Act (or any similar statute), then Agent may, in its discretion (subject only to applicable requirements of law), sell such Shares or part thereof by private sale in such manner and under such circumstances as Agent or Lenders may deem necessary or advisable, but subject to the other requirements of this Article 7, and shall not be required to effect such registration or to cause the same to be effected. Without limiting the generality of the foregoing, in any such event, Agent, at the direction of Lenders in their sole discretion, may (i) in accordance with applicable securities laws proceed to make such private sale notwithstanding that a registration statement for the purpose of registering such Shares or part thereof could be or shall have been filed under the Securities Act (or similar statute), (ii) approach and negotiate with a single possible purchaser to effect such sale, and (iii) restrict such sale to a purchaser who is an accredited investor under the Securities Act and who will represent and agree that such purchaser is purchasing for its own account, for investment and not with a view to the distribution or sale of such Shares or any part thereof. In addition to a private sale as provided above in this Article 7, if any of the Shares shall not be freely distributable to the public without registration under the Securities Act (or similar statute) at the time of any proposed sale pursuant to this Article 7, then Agent shall not be required to effect such registration or cause the same to be effected but, in its discretion (subject only to applicable requirements of law), may require that any sale hereunder (including a sale at auction) be conducted subject to restrictions:

(A) as to the financial sophistication and ability of any Person permitted to bid or purchase at any such sale;

(B) as to the content of legends to be placed upon any certificates representing the Shares sold in such sale, including restrictions on future transfer thereof;

(C) as to the representations required to be made by each Person bidding or purchasing at such sale relating to such Person's access to financial information about Borrower or any of its Subsidiaries and such Person's intentions as to the holding of the Shares so sold for investment for its own account and not with a view to the distribution thereof; and

(D) as to such other matters as Agent may, in its discretion, deem necessary or appropriate in order that such sale (notwithstanding any failure so to register) may be effected in compliance with the Bankruptcy Code and other laws affecting the enforcement of creditors' rights and the Securities Act and all applicable state securities laws.

(5) Borrower recognizes that Agent may be unable to effect a public sale of any or all the Shares and may be compelled to resort to one or more private sales thereof in accordance with clause (4) above. Borrower also acknowledges that any such private sale may result in prices and other terms less favorable to the seller than if such sale were a public sale and, notwithstanding such circumstances, agrees that any such private sale shall not be deemed to have been made in a commercially unreasonable manner solely by virtue of such sale being private. Agent shall be under no obligation to delay a sale of any of the Shares for the period of time necessary to permit the applicable Subsidiary to register such securities for public sale under the Securities Act, or under applicable state securities laws, even if Borrower and/or the Subsidiary would agree to do so.

7.4 Borrower's Obligations upon Default. Upon the written request of Agent (electronic mail being sufficient), at the direction of Lenders, after the occurrence and during the continuance of an Event of Default, Borrower will:

(a) Assemble and make available to Agent the Collateral at such place(s) as Agent shall reasonably designate, segregating all Collateral so that each item is capable of identification; and

(b) Subject to the rights of any lessor, permit Agent, by Agent's officers, employees, agents and representatives, to enter any premises where any Collateral is located, to take possession of the Collateral, to complete the processing, manufacture or repair of any Collateral, and to remove the Collateral, or to conduct any public or private sale of the Collateral, all without any liability of Agent or any Lender for rent or other compensation for the use of Borrower's premises.

ARTICLE 8 - SPECIAL COLLATERAL PROVISIONS

8.1 Compromise and Collection. Borrower and Agent recognize that setoffs, counterclaims, defenses and other claims may be asserted by obligors with respect to certain of the Rights to Payment; that certain of the Rights to Payment may be or become uncollectible in whole or in part; and that the expense and probability of success of litigating a disputed Right to Payment may exceed the amount that reasonably may be expected to be recovered with respect to such Right to Payment. Borrower hereby authorizes Agent, after and during the continuance of an Event of Default, to compromise with the obligor, accept in full payment of any Right to Payment such amount as Agent shall negotiate with the obligor, or abandon any Right to Payment. Any such action by Agent shall be considered commercially reasonable so long as Lenders have made the determination in good faith based on information known to them at the time Agent takes any such action.

8.2 Performance of Borrower's Obligations. Without having any obligation to do so, upon reasonable prior notice to Borrower, Agent may, at the direction of Lenders, perform or pay any obligation which Borrower has agreed to perform or pay under this Agreement, including, without limitation, the payment or discharge of taxes or Liens levied or placed on or threatened against the Collateral. In so performing or paying, Agent and Lenders shall determine the action to be taken and the amount necessary to discharge such obligations. Borrower shall reimburse Agent on demand for any amounts paid by Agent and each Lender pursuant to this Section, which amounts shall constitute Obligations secured by the Collateral and shall bear interest from the date of demand at the Default Rate.

8.3 Power of Attorney. For the purpose of protecting and preserving the Collateral and Agent's rights under this Agreement, Borrower hereby irrevocably appoints Agent, with full power of substitution, as its attorney-in-fact with full power and authority, after the occurrence and during the continuance of an Event of Default and upon written notice (electronic mail being sufficient) by Agent to Borrower, to do any act which Borrower is obligated to do hereunder; to exercise such rights with respect to the Collateral as Borrower might exercise; to use such Inventory, Equipment, Fixtures or other property as Borrower might use; to enter Borrower's premises; to give notice of Agent's security interest in, and to collect the Collateral; and before or after Default, to execute and file in Borrower's name any financing statements, amendments and continuation statements, account control agreements or other Security Documents necessary or desirable to create, maintain, perfect or continue the perfection of Agent's security interests in the Collateral. Borrower hereby ratifies all that Agent shall lawfully do or cause to be done by virtue of this appointment.

8.4 Authorization for Agent to Take Certain Action. The power of attorney created in Section 8.3 is a power coupled with an interest and shall be irrevocable. The powers conferred on Agent hereunder are solely to protect its interests in the Collateral and shall not impose any duty upon Agent to exercise such powers. Agent shall be accountable only for amounts that it actually receives as a result of the exercise of

such powers and in no event shall Agent or any of its directors, officers, employees, agents or representatives be responsible to Borrower for any act or failure to act, except for gross negligence or willful misconduct. After the occurrence and during the continuance of an Event of Default, Agent may exercise this power of attorney without notice to or assent of Borrower, in the name of Borrower, or in Agent's own name, from time to time in Agent's sole discretion and at Borrower's expense. To further carry out the terms of this Agreement, after the occurrence and during the continuance of an Event of Default and upon prior written notice by Agent to Borrower, Agent may, at the direction of Lenders, may:

(a) Execute any statements or documents or take possession of, and endorse and collect and receive delivery or payment of, any checks, drafts, notes, acceptances or other instruments and documents constituting Collateral, or constituting the payment of amounts due and to become due or any performance to be rendered with respect to the Collateral.

(b) Sign and endorse any invoices, freight or express bills, bills of lading, storage or warehouse receipts; drafts, certificates and statements under any commercial or standby letter of credit relating to Collateral; assignments, verifications and notices in connection with Accounts; or any other documents relating to the Collateral, including without limitation the Records.

(c) Use or operate Collateral or any other property of Borrower for the purpose of preserving or liquidating Collateral.

(d) File any claim or take any other action or proceeding in any court of law or equity or as otherwise deemed appropriate by Agent for the purpose of collecting any and all monies due or securing any performance to be rendered with respect to the Collateral.

(e) Commence, prosecute or defend any suits, actions or proceedings or as otherwise deemed appropriate by Agent for the purpose of protecting or collecting the Collateral. In furtherance of this right, upon the occurrence and during the continuance of an Event of Default, Agent may apply for the appointment of a receiver or similar official to operate Borrower's business.

(f) Prepare, adjust, execute, deliver and receive payment under insurance claims, and collect and receive payment of and endorse any instrument in payment of loss or returned premiums or any other insurance refund or return, and apply such amounts at Agent's sole discretion, toward repayment of the Obligations or replacement of the Collateral.

8.5 Application of Proceeds. Any Proceeds and other monies or property received by Agent pursuant to the terms of this Agreement or any Loan Document shall be applied as follows:

(a) First, to Agent, the aggregate amount of all costs, expenses, indemnities and other amounts required to be reimbursed to Agent, in its capacity as such, until paid in full;

(b) Second, to Agent, for the ratable benefit of Lenders (in accordance with the portion funded by each Lender), the aggregate amount of all Obligations arising on account of payments made by Agent in accordance with Section 8.2, until repaid in full;

(c) Third, to Lenders, ratably in accordance with principal amount of the Loans held by each Lender, an amount equal to the aggregate costs, expenses, indemnities or other amounts then required to be reimbursed to Lenders, until paid in full;

(d) Fourth, to Lenders, ratably in accordance with aggregate amount of any fees, premiums or similar payments due to each Lender in respect of the Loans held by such Lender, an amount equal to the aggregate fees, premiums or other similar such payments due to such Lender in respect of the Loans, until paid in full;

(e) Fifth, to Lenders, ratably in accordance with accrued and unpaid interest in respect of the Loans and the other Obligations due to each Lender, an amount equal to the aggregate accrued and unpaid interest on the Loans and other Obligations then due, until paid in full;

(f) Sixth, to Lenders, ratably in accordance outstanding principal due to each Lender in respect of the Loans, an amount equal to the aggregate principal outstanding in respect of the Loans then due, until paid in full;

(g) Seventh, to Agent and each Lender, ratably in accordance with the any other Obligations due to such Lender, an amount equal to all other Obligations due and payable to Agent and each Lender, until paid in full; and

(h) Last, the balance, if any, to Borrower or any designee thereof or as otherwise required by applicable law.

8.6 Deficiency. If the Proceeds of any disposition of the Collateral pursuant to the terms of this Agreement (other than any such disposition permitted by Section 6.5) are insufficient to cover all costs and expenses of such sale and the payment in full of all the Obligations, plus all other sums required to be expended or distributed by Agent to Lenders, then Borrower shall be liable for any such deficiency.

8.7 Agent Transfer. Upon the transfer of all or any part of the Obligations in accordance with the terms of this Agreement and the other Loan Documents, Agent may transfer all or part of the Collateral and shall be fully discharged thereafter from all liability and responsibility with respect to such Collateral so transferred, and the transferee shall be vested with all the rights and powers of Agent hereunder with respect to such Collateral so transferred, but with respect to any Collateral not so transferred, Agent shall retain all rights and powers hereby given.

8.8 Agent's Duties.

(a) Agent shall use reasonable care in the custody and preservation of any Collateral in its possession. Without limitation on other conduct which may be considered the exercise of reasonable care, Agent shall be deemed to have exercised reasonable care in the custody and preservation of such Collateral if such Collateral is accorded treatment substantially equal to that which Agent accords its own property, it being understood that Agent shall not have any responsibility for ascertaining or taking action with respect to calls, conversions, exchanges, maturities, declining value, tenders or other matters relative to any Collateral, regardless of whether Agent has or is deemed to have knowledge of such matters; or taking any necessary steps to preserve any rights against any Person with respect to any Collateral. Under no circumstances shall Agent be responsible for any injury or loss to the Collateral, or any part thereof, arising from any cause beyond the reasonable control of Agent.

(b) Agent may at any time deliver the Collateral or any part thereof to Borrower and the receipt of Borrower shall be a complete and full acquittance for the Collateral so delivered, and Agent shall thereafter be discharged from any liability or responsibility therefor.

(c) Neither Agent, nor any of its directors, officers, employees, agents, attorneys or any other person affiliated with or representing Agent shall be liable for any claims, demands, losses or damages, of any kind whatsoever, made, claimed, incurred or suffered by Borrower or any other party through the ordinary negligence of Agent, or any of its directors, officers, employees, agents, attorneys or any other person affiliated with or representing Agent.

8.9 Termination of Security Interests and Loan Documents. Upon the payment in full in cash of the Obligations (other than inchoate indemnity obligations), and if Lenders have no further obligations under its Commitment, the security interest granted hereby shall automatically terminate, all rights to the Collateral shall revert to Borrower and this Agreement and the other Loan Documents shall automatically terminate; provided that (i) those obligations, liabilities, covenants and terms that are expressly specified herein and in any other Loan Document as surviving that respective agreement's termination, including without limitation, Borrower's indemnity obligations set forth in this Agreement, shall continue to survive notwithstanding anything to the contrary set forth herein, and (ii) nothing set forth herein shall affect or be deemed to affect those obligations, liabilities, covenants and terms set forth in any warrant instrument issued to Lender's parent company or set forth in any other equity securities or convertible debt securities of Borrower acquired by Agent in connection with this Agreement. Upon any such termination, Agent shall return all Collateral in its possession or control to Borrower and, at Borrower's expense, execute and deliver to Borrower such documents as Borrower shall reasonably request in writing to evidence such termination.

ARTICLE 9 - GENERAL PROVISIONS

9.1 Notices. Any notice given by any party under any Loan Document shall be in writing and personally delivered, sent by overnight courier, or United States mail, postage prepaid, or sent by facsimile or electronic mail, or other authenticated message, charges prepaid, to the other party's or parties' addresses shown on the Supplement. Each party may change the address, facsimile number or email address to which notices, requests and other communications are to be sent by giving written notice of such change to each other party. Notice given by hand delivery shall be deemed received on the date delivered; if sent by overnight courier, on the next Business Day after delivery to the courier service; if by first class mail, on the third Business Day after deposit in the U.S. Mail; and if by facsimile or electronic mail, on the date of transmission.

9.2 Binding Effect. The Loan Documents shall be binding upon and inure to the benefit of Borrower, Lenders, Agent and their respective successors and assigns; provided, however, that Borrower may not

assign or transfer Borrower's rights or obligations under any Loan Document. Each Lender reserves the right to sell, assign, transfer, negotiate or grant participations in all or any part of, or any interest in, such Lender's rights and obligations under the Loan Documents provided that, so long as no Event of Default has occurred and is continuing, neither Lender shall not assign any of such rights or obligations to any competitor of Borrower. Without limiting the foregoing, any Lender may sell, assign, transfer, negotiate or grant participations in all or any part of, or any interest in, such Lender's rights and obligations under the Loan Documents to any Affiliate of such Lender. In connection with any of the foregoing, Lenders and Agent may disclose all documents and information which Lenders and Agent now or hereafter may have relating to the Loans, Borrower, or its business, provided that any Person who receives such information shall have agreed in writing in advance to maintain the confidentiality of such information on terms no less favorable to Borrower than are set forth in Section 9.13 hereof.

9.3 No Waiver. Any waiver, consent or approval by Agent and Lenders of any Event of Default or breach of any provision, condition, or covenant of any Loan Document must be in writing and shall be effective only to the extent set forth in writing. No waiver of any breach or default shall be deemed a waiver of any later breach or default of the same or any other provision of any Loan Document. No failure or delay on the part of Agent or any Lender in exercising any power, right, or privilege under any Loan Document shall operate as a waiver thereof, and no single or partial exercise of any such power, right, or privilege shall preclude any further exercise thereof or the exercise of any other power, right or privilege. Agent and each Lender has the right at its sole option to continue to accept interest and/or principal payments due under the Loan Documents after default, and such acceptance shall not constitute a waiver of said default or an extension of the maturity of any Loan unless Lenders agree otherwise in writing.

9.4 Rights Cumulative. All rights and remedies existing under the Loan Documents are cumulative to, and not exclusive of, any other rights or remedies available under contract or applicable law.

9.5 Unenforceable Provisions. Any provision of any Loan Document executed by Borrower which is prohibited or unenforceable in any jurisdiction, shall be so only as to such jurisdiction and only to the extent of such prohibition or unenforceability, but all the remaining provisions of any such Loan Document shall remain valid and enforceable.

9.6 Accounting Terms. Except as otherwise provided in this Agreement, accounting terms and financial covenants and information shall be determined and prepared in accordance with GAAP.

9.7 Indemnification; Exculpation. Borrower shall pay and protect, defend and indemnify each Lender, Agent and each Lender's and Agent's employees, officers, directors, shareholders, affiliates, correspondents, agents and representatives (other than Lenders, collectively **"Agents"**) against, and hold each Lender, Agent and each of such Agents harmless from, all claims, actions, proceedings and reasonable and documented out-of-pocket liabilities, damages, losses, expenses (including, without limitation, reasonable and documented out-of-pocket outside attorneys' fees and costs) and other amounts incurred by each Lender, Agent and each of such Agents, arising from (i) the matters contemplated by this Agreement or any other Loan Documents, (ii) any dispute between Borrower and a third party, or (iii) any contention that Borrower has failed to comply with any law, rule, regulation, order or directive applicable to Borrower's business; **provided, however**, that this indemnification shall not apply to any of the foregoing to the extent incurred as the result of any Lender's or any Agent's or any of such Agents' gross negligence, bad faith or willful misconduct. This indemnification shall survive the payment and satisfaction of all of Borrower's Obligations to Lenders.

9.8 Reimbursement. Borrower shall reimburse each Lender and Agent for all reasonable and documented out-of-pocket costs and expenses, including without limitation reasonable and documented out-of-pocket outside attorneys' fees and disbursements expended or incurred by each Lender and Agent in any arbitration, mediation, judicial reference, legal action or otherwise in connection with (a) the preparation and negotiation of the Loan Documents, (b) the amendment and enforcement of the Loan Documents, including without limitation during any workout, attempted workout, and/or in connection with the rendering of legal advice as to each Lender's and Agent's rights, remedies and obligations under the Loan Documents, (c) collecting any sum which becomes due to each Lender under any Loan Document, (d) any proceeding for declaratory relief, any counterclaim to any proceeding, or any appeal, or (e) the protection, preservation or enforcement of any rights of Lenders or Agent under the Loan Documents. For the purposes of this section, attorneys' fees shall include, without limitation, fees incurred in connection with the following: (1) contempt proceedings; (2) discovery; (3) any motion, proceeding or other activity of any kind in connection with an Insolvency

Proceeding; (4) garnishment, levy, and debtor and third party examinations; and (5) post-judgment motions and proceedings of any kind, including without limitation any activity taken to collect or enforce any judgment. All of the foregoing costs and expenses shall be payable promptly upon written demand (electronic mail being sufficient) by any Lender or Agent, and if not paid within forty-five (45) days of presentation of invoices shall bear interest at the Default Rate.

9.9 Execution in Counterparts; Electronic Signatures. This Agreement and the other Loan Documents may be executed in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same agreement. This Agreement and each of the other Loan Documents may be executed by electronic signatures. Borrower, Agent and Lenders expressly agree to conduct the transactions contemplated by this Agreement and the other Loan Documents by electronic means (including, without limitation, with respect to the execution, delivery, storage and transfer of this Agreement and each of the other Loan Documents by electronic means and to the enforceability of electronic Loan Documents). Delivery of an executed signature page to this Agreement and each of the other Loan Documents by facsimile or other electronic mail transmission (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com) shall be effective as delivery of a manually executed counterpart hereof and thereof, as applicable. The words "execution," "signed," "signature" and words of like import herein shall be deemed to include electronic signatures or the keeping of records in electronic form, each of which shall be of the same legal effect, validity and enforceability as a manually executed signature or the use of a paper-based recordkeeping systems, as the case may be, to the extent and as provided for in any applicable law, including, without limitation, any state law based on the Uniform Electronic Transactions Act.

9.10 Entire Agreement. The Loan Documents are intended by the parties as the final expression of their agreement and therefore contain the entire agreement between the parties and supersede all prior understandings or agreements concerning the subject matter hereof. This Agreement may be amended only in a writing signed by Borrower, Agent and each Lender.

9.11 Governing Law and Jurisdiction.

(a) THIS AGREEMENT AND THE LOAN DOCUMENTS SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE STATE OF CALIFORNIA.

(b) ANY LEGAL ACTION OR PROCEEDING WITH RESPECT TO THIS AGREEMENT OR ANY OTHER LOAN DOCUMENT MAY BE BROUGHT IN THE COURTS OF THE STATE OF CALIFORNIA OR OF THE UNITED STATES FOR THE NORTHERN DISTRICT OF CALIFORNIA, AND BY EXECUTION AND DELIVERY OF THIS AGREEMENT, EACH OF BORROWER, AGENT AND EACH LENDER CONSENTS, FOR ITSELF AND IN RESPECT OF ITS PROPERTY, TO THE NON-EXCLUSIVE JURISDICTION OF THOSE COURTS. EACH OF BORROWER, AGENT AND EACH LENDER IRREVOCABLY WAIVES ANY OBJECTION, INCLUDING ANY OBJECTION TO THE LAYING OF VENUE OR BASED ON THE GROUNDS OF FORUM NON CONVENIENS, WHICH IT MAY NOW OR HEREAFTER HAVE TO THE BRINGING OF ANY ACTION OR PROCEEDING IN SUCH JURISDICTION IN RESPECT OF THIS AGREEMENT OR ANY DOCUMENT RELATED HERETO. BORROWER, AGENT AND EACH LENDER EACH WAIVE PERSONAL SERVICE OF ANY SUMMONS, COMPLAINT OR OTHER PROCESS, WHICH MAY BE MADE BY ANY OTHER MEANS PERMITTED BY CALIFORNIA LAW.

9.12 Waiver of Jury Trial. TO THE EXTENT NOT PROHIBITED BY APPLICABLE LAW, BORROWER, AGENT AND EACH LENDER EACH WAIVES ITS RESPECTIVE RIGHTS TO A TRIAL BY JURY OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF OR RELATED TO THIS AGREEMENT, THE OTHER LOAN DOCUMENTS, OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY, IN ANY ACTION, PROCEEDING OR OTHER LITIGATION OF ANY TYPE BROUGHT BY ANY OF THE PARTIES AGAINST ANY OTHER PARTY OR ANY PARTICIPANT OR ASSIGNEE, WHETHER WITH RESPECT TO CONTRACT CLAIMS, TORT CLAIMS, OR OTHERWISE. BORROWER, AGENT AND EACH LENDER EACH AGREES THAT ANY SUCH CLAIM OR CAUSE OF ACTION SHALL BE TRIED BY A COURT TRIAL WITHOUT A JURY. WITHOUT LIMITING THE FOREGOING, THE PARTIES FURTHER AGREE THAT THEIR RESPECTIVE RIGHT TO A TRIAL BY JURY IS WAIVED BY OPERATION OF THIS SECTION AS TO ANY ACTION, COUNTERCLAIM OR OTHER PROCEEDING WHICH SEEMS, IN

WHOLE OR IN PART, TO CHALLENGE THE VALIDITY OR ENFORCEABILITY OF THIS AGREEMENT OR THE OTHER LOAN DOCUMENTS OR ANY PROVISION HEREOF OR THEREOF. THIS WAIVER SHALL APPLY TO ANY SUBSEQUENT AMENDMENTS, RENEWALS, SUPPLEMENTS OR MODIFICATIONS TO THIS AGREEMENT AND THE OTHER LOAN DOCUMENTS.

9.13 Confidentiality. Agent and each Lender agrees to hold in confidence all confidential information that it receives from Borrower pursuant to the Loan Documents, except for disclosure as shall be reasonably required: (a) to legal counsel and accountants for Agent and each Lender; (b) to other professional advisors to Agent and each Lender; (c) to regulatory officials having jurisdiction over Lender to the extent required by law; (d) to Agent's and each Lender's investors and prospective investors (subject to the same confidentiality obligation set forth herein), and in Agent's and each Lender's SEC filings as required by law; (e) as required by law or legal process or in connection with any legal proceeding to which Agent, any Lender and Borrower are adverse parties; (f) in connection with a disposition or proposed disposition of any or all of Agent's and any Lender's rights hereunder to any assignee or participant (subject to the same confidentiality obligation set forth herein); (g) to Agent's and each Lender's subsidiaries or Affiliates in connection with their business with Borrower (subject to the same confidentiality obligation set forth herein); (h) as required by valid order of a court of competent jurisdiction, administrative agency or governmental body, or by any applicable law, rule, regulation, subpoena, or any other administrative or legal process, or by applicable regulatory or professional standards, including in connection with any judicial or other proceeding involving Agent or any Lender relating to this Agreement and the transactions contemplated hereby; and (i) as required in connection with Agent's and any Lender's examination or audit. For purposes of this section, Agent, each Lender and Borrower agree that "confidential information" shall mean any information regarding or relating to Borrower other than: (i) information which is or becomes generally available to the public other than as result of a disclosure by Agent or any Lender in violation of this section, (ii) information which becomes available to Agent or any Lender from any other source (other than Borrower) which neither Agent nor the relevant Lender knows is bound by a confidentiality agreement with respect to the information made available, and (iii) information that Agent or such Lender knows on a non-confidential basis prior to Borrower disclosing it to Agent or such Lender. In addition, Borrower agrees that Agent and each Lender may use Borrower's name, logo and/or trademark in connection with certain promotional materials that Agent and any Lender may disseminate to the public, including, but are not limited to, brochures, internet website, press releases and any other materials relating to the fact that Agent and each Lender has a financing relationship with Borrower.

ARTICLE 10 - AGENCY.

10.1 Appointment. Each Lender hereby irrevocably appoints Avenue Capital Management II, L.P. to act on its behalf as the administrative agent hereunder and under the other Loan Documents and authorizes the Agent to take such actions on its behalf and to exercise such powers as are delegated to the Agent by the terms hereof or thereof, together with such actions and powers as are reasonably incidental thereto.

10.2 Indemnity. Each Lender agrees to indemnify the Agent in its capacity as such (to the extent not reimbursed by Borrowers and without limiting the obligation of Borrowers to do so), according to its respective Commitment percentage in effect on the date on which indemnification is sought under this Section 10.2, from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, costs, expenses or disbursements of any kind whatsoever that may at any time be imposed on, incurred by or asserted against the Agent in any way relating to or arising out of, this Agreement, a Supplement, any of the other Loan Documents or any documents contemplated by or referred to herein or therein or the transactions contemplated hereby or thereby or any action taken or omitted by the Agent under or in connection with any of the foregoing; The agreements in this Section shall survive the payment of each Loan and all other amounts payable hereunder. Agent shall not be liable for any action taken or not taken by it (i) with the consent or at the request of any Lender or as Agent shall believe in good faith shall be necessary, under the circumstances or (ii) in the absence of its own gross negligence or willful misconduct.

10.3 Duties. Agent shall not be responsible for or have any duty to ascertain or inquire into (i) any statement, warranty or representation made in or in connection with this Agreement or any other Loan Document, (ii) the contents of any certificate, report or other document delivered hereunder or thereunder or in connection herewith or therewith, (iii) the performance or observance of any of the covenants, agreements or other terms or conditions set forth herein or therein or the occurrence of any default or Event of Default, (iv)

the validity, enforceability, effectiveness or genuineness of this Agreement, any other Loan Document or any other agreement, instrument or document or (v) the satisfaction of any condition set forth in Section 4 or elsewhere herein, other than to confirm receipt of items expressly required to be delivered to the Agent.

10.4 Reliance by Agent. Agent may rely, and shall be fully protected in acting, or refraining to act, upon, any resolution, statement, certificate, instrument, opinion, report, notice, request, consent, order, bond or other paper or document that it has no reason to believe to be other than genuine and to have been signed or presented by the proper party or parties or, in the case of cables, telecopies and telexes, to have been sent by the proper party or parties. In the absence of its gross negligence or willful misconduct, Agent may conclusively rely, as to the truth of the statements and the correctness of the opinions expressed therein, upon any certificates or opinions furnished to Agent and conforming to the requirements of the Loan Agreement or any of the other Loan Documents. Agent may consult with counsel, and any opinion or legal advice of such counsel shall be full and complete authorization and protection in respect of any action taken, not taken or suffered by Agent hereunder or under any Loan Documents in accordance therewith. Agent shall have the right at any time to seek instructions concerning the administration of the Collateral from any court of competent jurisdiction. Agent shall not be under any obligation to exercise any of the rights or powers granted to Agent by this Agreement, the Loan Agreement and the other Loan Documents at the request or direction of Lenders unless Agent shall have been provided by Lenders with adequate security and indemnity against the costs, expenses and liabilities that may be incurred by it in compliance with such request or direction.

10.5 Collateral Agent. The Agent shall also act as the "collateral agent" under the Loan Documents, and each of the Lenders hereby irrevocably appoints and authorizes the Agent to act as the agent of such Lender for purposes of acquiring, holding and enforcing any and all Liens on Collateral granted by Borrowers to secure any of the Obligations. Each Lender hereby authorizes Agent, on behalf of and for the ratable benefit of Lenders, in its capacity as collateral agent, to enter into any of the Loan Documents as secured party for purposes of acquiring, holding and enforcing all Liens on Collateral (and any other collateral from time to time securing the Obligations), and as Agent for and representative of Lender thereunder, and each Lender agrees to be bound by the terms of each such document. All powers, rights and remedies under the Loan Documents may be exercised solely by Agent for the benefit of Lenders and Agent in accordance with the terms thereof. In the event of a foreclosure on any of the Collateral pursuant to a public or private sale, either Agent or any Lender may be the purchaser of any or all of such Collateral at any such sale and Agent, as agent for and representative of Lenders (but not any Lender or Lenders in its or their respective individual capacities unless Required Lenders shall otherwise agree in writing) shall be entitled (subject to the proviso at the end of this sentence), for the purpose of bidding and making settlement or payment of the purchase price for all or any portion of the Collateral sold at any such public sale, to use and apply any of the Obligations as a credit on account of the purchase price for any Collateral payable by Agent at such sale; provided however, that neither Agent nor any Lender shall "credit bid" at any foreclosure and/or other public or private sale absent the consent of the Required Lenders. Without limiting the generality of the foregoing, Agent is hereby expressly authorized to execute any and all documents (including releases) that bind Lenders with respect to (i) the Collateral and the rights of Lenders with respect thereto, as contemplated by and in accordance with the provisions of the Loan Documents, and (ii) any other subordination agreement with respect to any Subordinated Debt.

10.6 Successor Agents. Agent may resign upon thirty (30) days' notice to the Lenders and Borrowers. If Agent shall resign in its capacity under this Agreement and the other Loan Documents, then the Required Lenders shall appoint a successor agent, whereupon such successor agent shall succeed to the rights, powers and duties of Agent in its capacity, and the term "Agent" shall mean such successor agent effective upon such appointment and approval, and the former Agent's rights, powers and duties as Agent in its capacity shall be terminated, without any other or further act or deed on the part of such former Agent or any of the parties to this Agreement or any Lender. If no applicable successor agent has accepted appointment as such Agent in its capacity by the date that is twenty (20) days following such retiring Agent's notice of resignation, such retiring Agent's resignation shall nevertheless thereupon become effective and the Lenders shall assume and perform all of the duties of such Agent hereunder until such time, if any, as the Required Lenders appoint a successor agent as provided for above. After any retiring Agent's resignation as Agent, the provisions of this Section 10 shall inure to its benefit as to any actions taken or omitted to be taken by it while it was an Agent under this Agreement and the other Loan Documents.

ARTICLE 11 - DEFINITIONS

The definitions appearing in this Agreement or any Supplement shall be applicable to both the singular and plural forms of the defined terms:

"Account" means any "account," as such term is defined in the UCC, now owned or hereafter acquired by Borrower or in which Borrower now holds or hereafter acquires any interest and, in any event, shall include, without limitation, all accounts receivable, book debts and other forms of obligations (other than forms of obligations evidenced by Chattel Paper, Documents or Instruments) now owned or hereafter received or acquired by or belonging or owing to Borrower (including, without limitation, under any trade name, style or division thereof) whether arising out of goods sold or services rendered by Borrower or from any other transaction, whether or not the same involves the sale of goods or services by Borrower (including, without limitation, any such obligation that may be characterized as an account or contract right under the UCC) and all of Borrower's rights in, to and under all purchase orders or receipts now owned or hereafter acquired by it for goods or services, and all of Borrower's rights to any goods represented by any of the foregoing (including, without limitation, unpaid seller's rights of rescission, replevin, reclamation and stoppage in transit and rights to returned, reclaimed or repossessed goods), and all monies due or to become due to Borrower under all purchase orders and contracts for the sale of goods or the performance of services or both by Borrower or in connection with any other transaction (whether or not yet earned by performance on the part of Borrower), now in existence or hereafter occurring, including, without limitation, the right to receive the proceeds of said purchase orders and contracts, and all collateral security and guarantees of any kind given by any Person with respect to any of the foregoing.

"Affiliate" means any Person which directly or indirectly controls, is controlled by, or is under common control with Borrower. "Control," "controlled by" and "under common control with" mean direct or indirect possession of the power to direct or cause the direction of management or policies (whether through ownership of voting securities, by contract or otherwise); provided, that control shall be conclusively presumed when any Person or affiliated group directly or indirectly owns five percent (5%) or more of the securities having ordinary voting power for the election of directors of a corporation.

"Agreement" means this Loan and Security Agreement and each Supplement thereto, as each may be amended or supplemented from time to time.

"Bankruptcy Code" means the Federal Bankruptcy Reform Act of 1978 (11 U.S.C. §101, et seq.), as amended.

"Basic Interest" means the rate of interest payable on the outstanding balance of each Loan at the applicable Designated Rate.

"Borrowing Date" means the Business Day on which the proceeds of a Loan are disbursed by Lenders.

"Borrowing Request" means a written request from Borrower in substantially the form of Exhibit "B" to the Supplement, requesting the funding of one or more Loans on a particular Borrowing Date.

"Business Day" means any day other than a Saturday, Sunday or other day on which commercial banks in New York City or San Francisco are authorized or required by law to close.

"Change of Control" means (a) any sale, license, or other disposition of all or substantially all of the assets of Borrower, in each case, to the extent prohibited by this Agreement; (b) any reorganization, consolidation, merger or other similar transaction involving Borrower, in each case, to the extent prohibited by this Agreement; or (c) any transaction or series of related transactions in which any Person or two or more Persons acting in concert shall have acquired by contract or otherwise, the power to control the management of Borrower, or to control the equity interests of Borrower entitled to vote for members of the Board of Directors or equivalent governing body of Borrower on a fully-diluted basis (and taking into account all such securities that such Person or Persons have the right to acquire pursuant to any option right) representing fifty percent (50.00%) or more of the combined voting power of such securities.

"Chattel Paper" means any "chattel paper," as such term is defined in the UCC, now owned or hereafter acquired by Borrower or in which Borrower now holds or hereafter acquires any interest.

"Closing Date" means the date of this Agreement.

"Collateral" means all of Borrower's right, title and interest in and to the following property, whether now owned or hereafter acquired and wherever located: (a) all Receivables; (b) all Equipment; (c) all Fixtures; (d)

all General Intangibles; (e) all Inventory; (f) all Investment Property; (g) all Deposit Accounts; (h) all Shares; (i) all other Goods and personal property of Borrower, whether tangible or intangible and whether now or hereafter owned or existing, leased, consigned by or to, or acquired by, Borrower and wherever located; (j) all Records; and (k) all Proceeds of each of the foregoing and all accessions to, substitutions and replacements for, and rents, profits and products of each of the foregoing.

Notwithstanding the foregoing the term "Collateral" shall not include: (i) more than sixty-five percent (65%) of the issued and outstanding capital stock, membership units or other securities entitled to vote owned or held of record by Borrower in any Subsidiary that is a controlled foreign corporation (as defined in the Internal Revenue Code), provided that the Collateral shall include one hundred percent (100%) of the issued and outstanding non-voting capital stock of such Subsidiary; (ii) "intent-to-use" trademarks at all times prior to the first use thereof, whether by the actual use thereof in commerce, the recording of a statement of use with the United States Patent and Trademark Office or otherwise, but only to the extent the granting of a security interest in such "intent to use" trademarks would be contrary to applicable law; (iii) any contract, Instrument or Chattel Paper in which Borrower has any right, title or interest if and to the extent such contract, Instrument or Chattel Paper includes a provision containing a restriction on assignment such that the creation of a security interest in the right, title or interest of Borrower therein would be prohibited and would, in and of itself, cause or result in a default thereunder enabling another person party to such contract, Instrument or Chattel Paper to enforce any remedy with respect thereto; provided, however, that the foregoing exclusion shall not apply if (A) such prohibition has been waived or such other person has otherwise consented to the creation hereunder of a security interest in such contract, Instrument or Chattel Paper, or (B) such prohibition would be rendered ineffective pursuant to Sections 9-407(a) or 9-408(a) of the UCC, as applicable and as then in effect in any relevant jurisdiction, or any other applicable law (including the Bankruptcy Code or principles of equity); provided, further, that immediately upon the ineffectiveness, lapse or termination of any such provision, the term "Collateral" shall include, and Borrower shall be deemed to have granted a security interest in, all its rights, title and interests in and to such contract, Instrument or Chattel Paper as if such provision had never been in effect; and provided further that the foregoing exclusion shall in no way be construed so as to limit, impair or otherwise affect Agent's unconditional continuing security interest in and to all rights, title and interests of Borrower in or to any payment obligations or other rights to receive monies due or to become due under any such contract, Instrument or Chattel Paper and in any such monies and other proceeds of such contract, Instrument or Chattel Paper; (iv) motor vehicles and other assets subject to certificates of title; or (v) letter-of-credit rights (other than to the extent such rights can be perfected by filing a UCC-1 financing statement) or commercial tort claims with value less than Two Hundred Fifty Thousand Dollars ($250,000).

"Commitment" means the obligation of Lenders to make Loans to Borrower up to the aggregate principal amount set forth in the Supplement.

"Copyright License" means any written agreement granting any right to use any Copyright or Copyright registration now owned or hereafter acquired by Borrower or in which Borrower now holds or hereafter acquires any interest.

"Copyrights" means all of the following now owned or hereafter acquired by Borrower or in which Borrower now holds or hereafter acquires any interest: (i) all copyrights, whether registered or unregistered, held pursuant to the laws of the United States, any State thereof or of any other country; (ii) all registrations, applications and recordings in the United States Copyright Office or in any similar office or agency of the United States, any State thereof or any other country; (iii) all continuations, renewals or extensions thereof; and (iv) any registrations to be issued under any pending applications.

"Default" means an event which with the giving of notice, passage of time, or both would constitute an Event of Default.

"Default Rate" means the applicable Designated Rate plus five percent (5%) per annum.

"Deposit Accounts" means any "deposit accounts," as such term is defined in the UCC, now owned or hereafter acquired by Borrower or in which Borrower now holds or hereafter acquires any interest.

"Designated Rate" means the rate of interest per annum described in the Supplement as being applicable to an outstanding Loan from time to time.

"Documents" means any "documents," as such term is defined in the UCC, now owned or hereafter acquired by Borrower or in which Borrower now holds or hereafter acquires any interest.

"Dollars" or **"$"** means lawful currency of the United States.

"Environmental Laws" means all federal, state or local laws, statutes, common law duties, rules, regulations, ordinances and codes, together with all administrative orders, directed duties, requests, licenses, authorizations and permits of, and agreements with, any governmental authorities, in each case relating to environmental, health, or safety matters.

"Equipment" means any "equipment," as such term is defined in the UCC, now owned or hereafter acquired by Borrower or in which Borrower now holds or hereafter acquires any interest and any and all additions, substitutions and replacements of any of the foregoing, wherever located, together with all attachments, components, parts, equipment and accessories installed thereon or affixed thereto.

"Event of Default" means any event described in Section 7.1.

"FDA" means the United States Food and Drug Administration.

"Fixtures" means any "fixtures," as such term is defined in the UCC, now owned or hereafter acquired by Borrower or in which Borrower now holds or hereafter acquires any interest.

"GAAP" means generally accepted accounting principles and practices consistent with those principles and practices promulgated or adopted by the Financial Accounting Standards Board and the Board of the American Institute of Certified Public Accountants, their respective predecessors and successors. Each accounting term used but not otherwise expressly defined herein shall have the meaning given it by GAAP.

"General Intangibles" means any "general intangibles," as such term is defined in the UCC, now owned or hereafter acquired by Borrower or in which Borrower now holds or hereafter acquires any interest and, in any event, shall include, without limitation, all right, title and interest that Borrower may now or hereafter have in or under any contract, all customer lists, Copyrights, Trademarks, Patents, websites, domain names, and all applications therefor and reissues, extensions, or renewals thereof, other items of, and rights to, Intellectual Property, interests in partnerships, joint ventures and other business associations, Licenses, permits, trade secrets, proprietary or confidential information, inventions (whether or not patented or patentable), technical information, procedures, designs, knowledge, know-how, software, data bases, data, skill, expertise, recipes, experience, processes, models, drawings, materials and records, goodwill (including, without limitation, the goodwill associated with any Trademark, Trademark registration or Trademark licensed under any Trademark License), claims in or under insurance policies, including unearned premiums, uncertificated securities, money, cash or cash equivalents, deposit, checking and other bank accounts, rights to sue for past, present and future infringement of Copyrights, Trademarks and Patents, rights to receive tax refunds and other payments and rights of indemnification.

"Goods" means any "goods," as such term is defined in the UCC, now owned or hereafter acquired by Borrower or in which Borrower now holds or hereafter acquires any interest.

"Indebtedness" of any Person means at any date, without duplication and without regard to whether matured or unmatured, absolute or contingent: (i) all obligations of such Person for borrowed money; (ii) all obligations of such Person evidenced by bonds, debentures, notes, or other similar instruments; (iii) all obligations of such Person to pay the deferred purchase price of property or services, except trade accounts payable arising in the ordinary course of business; (iv) all obligations of such Person as lessee under capital leases; (v) all obligations of such Person to reimburse or prepay any bank or other Person in respect of amounts paid under a letter of credit, banker's acceptance, or similar instrument, whether drawn or undrawn; (vi) all obligations of such Person to purchase securities which arise out of or in connection with the sale of the same or substantially similar securities; (vii) all obligations of such Person to purchase, redeem, exchange, convert or otherwise acquire for value any capital stock of such Person or any warrants, rights or options to acquire such capital stock, now or hereafter outstanding, except to the extent that such obligations remain performable solely at the option of such Person; (viii) all obligations to repurchase assets previously sold (including any obligation to repurchase any accounts or chattel paper under any factoring, receivables purchase, or similar arrangement); (ix) obligations of such Person under interest rate swap, cap, collar or similar hedging arrangements; and (x) all obligations of others of any type described in clause (i) through clause (ix) above guaranteed by such Person.

"Insolvency Proceeding" means with respect to a Person (a) any case, action or proceeding before any court or other governmental authority relating to bankruptcy, reorganization, insolvency, liquidation, receivership, dissolution, winding-up or relief of debtors with respect to such Person, or (b) any general assignment for the benefit of creditors, composition,

marshalling of assets for creditors, or other, similar arrangement in respect of such Person's creditors generally or any substantial portion of its creditors, undertaken under U.S. Federal, state or foreign law, including the Bankruptcy Code, but in each case, excluding any avoidance or similar action against such Person commenced by an assignee for the benefit of creditors, bankruptcy trustee, debtor in possession, or other representative of another Person or such other Person's estate.

"Instruments" means any "instrument," as such term is defined in the UCC, now owned or hereafter acquired by Borrower or in which Borrower now holds or hereafter acquires any interest.

"Intellectual Property" means all of Borrower's Copyrights, Trademarks, Patents, Licenses, trade secrets, source codes, customer lists, proprietary or confidential information, inventions (whether or not patented or patentable), technical information, procedures, designs, knowledge, know-how, software, data bases, skill, expertise, experience, processes, models, drawings, materials, records and goodwill associated with the foregoing.

"Intellectual Property Security Agreement" means any Intellectual Property Security Agreement executed and delivered by Borrower in favor of Agent, as the same may be amended, restated, amended and restated, supplemented, or otherwise modified from time to time.

"Inventory" means any "inventory," as such term is defined in the UCC, wherever located, now owned or hereafter acquired by Borrower or in which Borrower now holds or hereafter acquires any interest, and, in any event, shall include, without limitation, all inventory, goods and other personal property that are held by or on behalf of Borrower for sale or lease or are furnished or are to be furnished under a contract of service or that constitute raw materials, work in process or materials used or consumed or to be used or consumed in Borrower's business, or the processing, packaging, promotion, delivery or shipping of the same, and all finished goods, whether or not the same is in transit or in the constructive, actual or exclusive possession of Borrower or is held by others for Borrower's account, including, without limitation, all goods covered by purchase orders and contracts with suppliers and all goods billed and held by suppliers and all such property that may be in the possession or custody of any carriers, forwarding agents, truckers, warehousemen, vendors, selling agents or other Persons.

"Investment Property" means any "investment property," as such term is defined in the UCC, now owned or hereafter acquired by Borrower or in which Borrower now holds or hereafter acquires any interest.

"Letter of Credit Rights" means any "letter of credit rights," as such term is defined in the UCC, now owned or hereafter acquired by Borrower or in which Borrower now holds or hereafter acquires any interest, including any right to payment under any letter of credit.

"License" means any Copyright License, Patent License, Trademark License or other license of rights or interests now held or hereafter acquired by Borrower or in which Borrower now holds or hereafter acquires any interest and any renewals or extensions thereof.

"Lien" means any mortgage, deed of trust, pledge, hypothecation, assignment for security, security interest, encumbrance, levy, lien or charge of any kind, whether voluntarily incurred or arising by operation of law or otherwise, against any property, any conditional sale or other title retention agreement, any lease in the nature of a security interest, and the filing of any financing statement (other than a precautionary financing statement with respect to a lease that is not in the nature of a security interest) under the UCC or comparable law of any jurisdiction.

"Loan" means an extension of credit by any Lender under this Agreement.

"Loan Documents" means, individually and collectively, this Loan and Security Agreement, each Supplement, each Note, any Intellectual Property Security Agreement, any other security or pledge agreement(s), any Warrant issued by Borrower in connection with this Agreement, and all other contracts, instruments, addenda and documents executed in connection with this Agreement or the extensions of credit which are the subject of this Agreement.

"Material Adverse Effect" or "**Material Adverse Change**" means (a) a material adverse change in, or a material adverse effect upon, the results of operations, business, properties, or financial condition of Borrower; (b) a material impairment of the ability of Borrower to perform under any Loan Document; or (c) a material adverse effect upon the legality, validity, binding effect or enforceability against Borrower of any Loan Document.

"Mydcombi NDA" means that certain New Drug Application dated as of November 8, 2022.

"Note" means a promissory note substantially in the form attached to the Supplement as Exhibit "A", executed by Borrower evidencing the applicable Loan.

"Obligations" means all debts, obligations and liabilities of Borrower to Lender now or hereafter made, incurred or created under, pursuant to or in connection with this Agreement or any other Loan Document (other than the Warrant), whether voluntary or involuntary and however arising or evidenced, whether direct or acquired by Lender by assignment or succession, whether due or not due, absolute or contingent, liquidated or unliquidated, determined or undetermined, and whether Borrower may be liable individually or jointly, or whether recovery upon such debt may be or become barred by any statute of limitations or otherwise unenforceable; and all renewals, extensions and modifications thereof; and all attorneys' fees and costs incurred by Lender in connection with the collection and enforcement thereof as provided for in any such Loan Document.

"Patent License" means any written agreement granting any right with respect to any invention on which a Patent is in existence now owned or hereafter acquired by Borrower or in which Borrower now holds or hereafter acquires any interest.

"Patents" means all of the following property now owned or hereafter acquired by Borrower or in which Borrower now holds or hereafter acquires any interest: (a) all letters patent of, or rights corresponding thereto in, the United States or any other country, all registrations and recordings thereof, and all applications for letters patent of, or rights corresponding thereto in, the United States or any other country, including, without limitation, registrations, recordings and applications in the United States Patent and Trademark Office or in any similar office or agency of the United States, any State thereof or any other country; (b) all reissues, continuations, continuations-in-part or extensions thereof; (c) all petty patents, divisionals, and patents of addition; and (d) all patents to be issued under any such applications.

"Permitted Indebtedness" means:

(a) Indebtedness incurred for the acquisition of supplies, inventory or other property or services on normal trade credit;

(b) Indebtedness incurred pursuant to one or more transactions permitted under Section 6.4;

(c) Indebtedness of Borrower under this Agreement;

(d) Subordinated Debt;

(e) any Indebtedness approved by Agent prior to the Closing Date as shown on Schedule 6.1;

(f) Indebtedness secured by a lien described in clause (c) of the defined term "Permitted Liens" not to exceed One Hundred Fifty Thousand Dollars ($150,000) in aggregate principal amount outstanding at any time;

(g) Indebtedness incurred under corporate credit cards not to exceed One Hundred Thousand Dollars ($100,000) in aggregate principal amount outstanding at any time;

(h) guaranties and similar surety obligations in respect of Indebtedness otherwise constituting Permitted Indebtedness;

(i) Indebtedness in respect of performance bonds, bid bonds, appeal bonds, surety bonds and similar obligations, in each case provided in the ordinary course of business;

(j) Indebtedness in respect of netting services, overdraft protections and otherwise in connection with deposit accounts in the ordinary course of business;

(k) unsecured Indebtedness to pay the deferred purchase price of goods or services or progress payments in connection with such goods and services; provided that such obligations are incurred in the ordinary course of business;

(l) Indebtedness consisting of (i) obligations to pay insurance premiums or (ii) take or pay obligations contained in supply agreements, in each case arising in the ordinary course of business;

(m) Indebtedness representing deferred compensation to officers, directors or employees incurred in the ordinary course of business;

(n) Indebtedness representing any Taxes to the extent such Taxes are being contested by the Loan Parties in good faith by appropriate proceedings and adequate reserves are being maintained by the applicable Person in accordance with GAAP;

(o) extensions, refinancings and renewals of any of the foregoing; provided that the principal amount thereof is not increased except by an amount equal to unpaid accrued interest, fees and premium; and

(p) other unsecured Indebtedness in an aggregate principal amount not exceeding One Hundred Thousand ($100,000) at any time outstanding.

"Permitted Investment" means:

(a) accounts receivable in the ordinary course of Borrower's business;

(b) Investments in domestic certificates of deposit issued by, and other domestic investments with, financial institutions organized under the laws of the United States or a state thereof, having at least One Hundred Million Dollars ($100,000,000) in capital and a rating of at least "investment grade" or "A" by Moody's or any successor rating agency;

(c) Investments in marketable obligations of the United States of America and in open market commercial paper given the highest credit rating by a national credit agency and maturing not more than one year from the creation thereof;

(d) advances to employees incurred in the ordinary course of business not to exceed One Hundred Thousand Dollars ($100,000) in the aggregate outstanding at any time;

(e) Investments in joint ventures, strategic alliances, licensing and similar arrangements customary in Borrower's industry and which do not require Borrower to assume or otherwise become liable for the obligations of any third party not directly related to or arising out of such arrangement or, without the prior written consent of Agent, require Borrower to transfer ownership of non-cash assets to such joint venture or other entity;

(f) Investments in (i) one or more wholly-owned domestic Subsidiaries of Borrower, so long as in accordance with Section 6.14(a) of this Agreement, each such Person has been made a co-borrower hereunder or has executed and delivered to Agent an agreement, in form and substance reasonably satisfactory to Agent, containing a guaranty of the Obligations, and (ii) one or more wholly-owned foreign Subsidiaries of Borrower with the prior written consent of Agent;

(g) Investments in existence on the Closing Date as shown on Schedule 6.6 and any extension, refinancing or renewal of such Investments, so long as the aggregate amount of all Investments pursuant to this clause (g) is not increased at any time above the amount of such Investments existing on the date hereof;

(h) Investments accepted in connection with Transfers permitted by Section 6.5;

(i) loans to employees, officers or directors relating to the purchase of equity securities of Borrower pursuant to employee stock purchase plans or agreements approved by Borrower's Board of Directors, limited to an aggregate total of One Hundred Thousand Dollars ($100,000) at any time outstanding;

(j) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of Borrower's business;

(k) Investments permitted under Section 6.11;

(l) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions to, customers and suppliers in the ordinary course of business;

(m) Investments by wholly owned Subsidiaries in other wholly owned Subsidiaries or in Borrower; and

(n) other investments in an aggregate amount not to exceed One Hundred Thousand Dollars ($100,000) at any time outstanding.

"Permitted Lien" means:

(a) involuntary Liens which, in the aggregate, would not have a Material Adverse Effect and which in any event would not exceed, in the aggregate, the Threshold Amount;

(b) Liens for current taxes or other governmental or regulatory assessments which are not delinquent, or which are contested in good faith by the appropriate procedures and for which appropriate reserves are maintained;

(c) security interests on any property held or acquired by Borrower in the ordinary course of business securing Indebtedness incurred or assumed for the purpose of financing all or any part of the cost of acquiring such property; provided, that such Lien attaches solely to the property acquired with such Indebtedness and that the principal amount of such Indebtedness does not exceed one hundred percent (100%) of the cost of such property;

(d) Liens in favor of Agent;

(e) bankers' liens, rights of setoff and similar Liens incurred on deposits made in the ordinary course of business as long as an account control agreement (or equivalent) for each account in which such deposits are held in a form acceptable to Agent has been executed and delivered to Agent to the extent required under Section 6.11;

(f) materialmen's, mechanics', repairmen's, warehousemen's, carriers', landlord's (subject to Section 5.9(e) hereof), employees' or other like Liens arising in the ordinary course of business and which are not delinquent for more than forty-five (45) days or are being contested in good faith by appropriate proceedings;

(g) any judgment, attachment or similar Lien, unless the judgment it secures exceeds the Threshold Amount and has not been satisfied, vacated or stayed pending appeal within thirty (30) days of the entry thereof;

(h) licenses or sublicenses of Intellectual Property in accordance with the terms of Section 6.5 hereof;

(i) Liens securing Subordinated Debt;

(j) Liens which have been approved by Agent in writing prior to the Closing Date, as shown on Schedule 6.2 hereto;

(k) the interests of licensors under inbound licenses to Borrower;

(l) the interests of sub-lessees under subleases of real property;

(m) Liens to secure payment of workers' compensation, employment insurance, old-age pensions, social security and other like obligations incurred in the ordinary course of business (other than Liens imposed by ERISA);

(n) deposits to secure the performance of bids, trade contracts (other than for Indebtedness), leases (other than capital lease obligations), statutory obligations, surety and appeal bonds, performance bonds and other obligations of a like nature arising as a matter of law and incurred in the ordinary course of business;

(o) zoning restrictions, easements, rights of way, restrictions on use of real property and other similar encumbrances incurred in the ordinary course of business which, in the aggregate, are not substantial in amount and do not materially detract from the value of the property subject thereto or interfere with the ordinary conduct of the business of the Borrower or any of its Subsidiaries;

(p) pledges and deposits in the ordinary course of business securing the financing of the insurance premiums under insurance policies, payable to insurance carriers that provide insurance to the Borrower or any of its Subsidiaries; and

(q) Liens arising from precautionary Uniform Commercial Code financing statement or similar filings made in respect of operating leases; and

(r) other Liens in an aggregate amount not to exceed Fifty Thousand Dollars ($50,000) at any time outstanding.

"Person" means any individual, sole proprietorship, partnership, joint venture, trust, unincorporated organization, association, corporation, limited liability company, institution, public benefit corporation, other entity or government (whether federal, state, county, city, municipal, local, foreign, or otherwise, including any instrumentality, division, agency, body or department thereof).

"Proceeds" means "proceeds," as such term is defined in the UCC and, in any event, shall include, without limitation, (a) any and all Accounts, Chattel Paper, Instruments, cash or other forms of money or currency or other proceeds payable to Borrower from time to time in respect of the Collateral, (b) any and all proceeds of any insurance, indemnity, warranty or guaranty payable to Borrower from time to time with respect to any of the Collateral, (c) any and all payments (in any form whatsoever) made or due and payable to Borrower from time to time in connection with any requisition, confiscation, condemnation, seizure or forfeiture of all or any part of the Collateral by any governmental authority (or any Person acting under color of governmental authority), (d) any claim of Borrower against third parties (i) for past, present or future infringement of any Copyright, Patent or Patent License or (ii) for past, present or future infringement or dilution of any Trademark or Trademark License or for injury to the goodwill associated with any Trademark, Trademark registration or Trademark licensed under any Trademark License and (e) any and all other amounts from time to time paid or payable under or in connection with any of the Collateral.

"Receivables" means all of Borrower's Accounts, Instruments, Documents, Chattel Paper, Supporting

Obligations, and letters of credit and Letter of Credit Rights.

"Records" means all Borrower's computer programs, software, hardware, source codes and data processing information, all written documents, books, invoices, ledger sheets, financial information and statements, and all other writings concerning Borrower's business.

"Related Person" means any Affiliate of Borrower, or any officer, employee, director or equity security holder of Borrower or any Affiliate.

"Rights to Payment" means all Borrower's accounts, instruments, contract rights, documents, chattel paper and all other rights to payment, including, without limitation, the Accounts, all negotiable certificates of deposit and all rights to payment under any Patent License, any Trademark License, or any commercial or standby letter of credit.

"Security Documents" means this Loan and Security Agreement, the Supplement hereto, the Intellectual Property Security Agreement, and any and all account control agreements, collateral assignments, chattel mortgages, financing statements, amendments to any of the foregoing and other documents from time to time executed or filed to create, perfect or maintain the perfection of Agent's Liens on the Collateral.

"Shares" means: (a) one hundred percent (100%) of the issued and outstanding capital stock, membership units or other securities owned or held of record by Borrower in any Subsidiary that is not a controlled foreign corporation (as defined in the Internal Revenue Code), and (b) 65% of the issued and outstanding capital stock, membership units or other securities entitled to vote owned or held of record by Borrower in any Subsidiary that is a controlled foreign corporation (as defined in the Internal Revenue Code).

"Subordinated Debt" means Indebtedness (i) approved by Lenders; and (ii) where the holder's right to payment of such Indebtedness, the priority of any Lien securing the same, and the rights of the holder thereof to enforce remedies against Borrower following default have been made subordinate to the Liens of Agent and to the prior payment to Lenders of the Obligations, either (A) pursuant to a written subordination agreement approved by Agent in its sole but reasonable discretion or (B) on terms otherwise approved by Agent in its sole but reasonable discretion.

"Subsidiary" means any Person a majority of the equity ownership or voting stock of which is directly or indirectly now owned or hereafter acquired by Borrower or by one or more other Subsidiaries.

"Supplement" means that certain supplement to the Loan and Security Agreement, as the same may be amended, restated, amended and restated, supplemented, or otherwise modified from time to time, and any other supplements entered into between Borrower, Agent and Lenders, as the same may be amended, restated, amended and restated, supplemented, or otherwise modified from time to time.

"Supporting Obligations" means any "supporting obligations," as such term is defined in the UCC, now owned or hereafter acquired by Borrower or in which Borrower now holds or hereafter acquires any interest.

"Termination Date" has the meaning specified in the Supplement.

"Threshold Amount" has the meaning specified in the Supplement.

"Trademark License" means any written agreement granting any right to use any Trademark or Trademark registration now owned or hereafter acquired by Borrower or in which Borrower now holds or hereafter acquires any interest.

"Trademarks" means all of the following property now owned or hereafter acquired by Borrower or in which Borrower now holds or hereafter acquires any interest: (a) all trademarks, tradenames, corporate names, business names, trade styles, service marks, logos, other source or business identifiers, prints and labels on which any of the foregoing have appeared or appear, designs and general intangibles of like nature, now existing or hereafter adopted or acquired, all registrations and recordings thereof, and any applications in connection therewith, including, without limitation, registrations, recordings and applications in the United States Patent and Trademark Office or in any similar office or agency of the United States, any State thereof or any other country or any political subdivision thereof and (b) reissues, extensions or renewals thereof.

"UCC" means the Uniform Commercial Code as the same may, from time to time, be in effect in the State of California; provided, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection or priority of, or remedies with respect to, Agent's Lien on any Collateral is governed by the Uniform Commercial Code as enacted and in effect in a jurisdiction other than the State of California, the term "UCC" shall mean the Uniform Commercial Code as enacted and in effect in such other jurisdiction

solely for purposes of the provisions thereof relating to such attachment, perfection, priority or remedies and for purposes of definitions related to such provisions. Unless otherwise defined herein, terms that are defined in the UCC and used herein shall have the meanings given to them in the UCC.

[Signature page follows]

[Signature page to Loan and Security Agreement]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date first above written.

BORROWER:

EYENOVIA, INC.

By: /s/ John Gandolfo
Name: John P. Gandolfo
Title: Chief Financial Officer

AGENT:

AVENUE CAPITAL MANAGEMENT II, L.P.

By: Avenue Capital Management II GenPar, LLC
Its: General Partner

By: /s/ Sonia Gardner
Name: Sonia Gardner
Title: Member

[Signatures continued, next page]

LENDERS:

AVENUE VENTURE OPPORTUNITIES FUND, L.P.

By: Avenue Venture Opportunities Partners, LLC
Its: General Partner

By: /s/ Sonia Gardner
Name: Sonia Gardner
Title: Authorized Signatory

AVENUE VENTURE OPPORTUNITIES FUND II, L.P.

By: Avenue Venture Opportunities Partners II, LLC
Its: General Partner

By: /s/ Sonia Gardner
Name: Sonia Gardner
Title: Authorized Signatory

[Schedules to Loan and Security Agreement follow]

Schedules to
Loan and Security Agreement
dated as of November __, 2022
between
Eyenovia, Inc.
Avenue Capital Management II, L.P., as Agent
and
the Lenders from time to time party thereto

Schedule of Exceptions

See attachment hereto.

Schedule 6.1. Permitted Indebtedness

None.

Schedule 6.2. Permitted Liens

None.

Schedule 6.6. Permitted Investments

None.

SUPPLEMENT
to the
Loan and Security Agreement
dated as of November 22, 2022
between
EYENOVIA, INC. ("Borrower")
and

AVENUE CAPITAL MANAGEMENT II, L.P.,
a Delaware limited partnership,
as administrative agent and collateral agent (in such capacity "Agent")
and

AVENUE VENTURE OPPORTUNITIES FUND, L.P. II,
a Delaware limited partnership ("Avenue 2"), as a lender
and

AVENUE VENTURE OPPORTUNITIES FUND, L.P.,
a Delaware limited partnership ("Avenue"), as a lender
(together with Avenue 2, each a "Lender" and collectively, "Lenders")

This is a Supplement identified in the document entitled Loan and Security Agreement, dated as of November 22, 2022 (as amended, restated, amended and restated, supplemented and modified from time to time, the **"Loan and Security Agreement"**), by and among Borrower, Lenders and Agent. All capitalized terms used in this Supplement and not otherwise defined in this Supplement have the meanings ascribed to them in Article 10 of the Loan and Security Agreement, which is incorporated in its entirety into this Supplement. In the event of any inconsistency between the provisions of the Loan and Security Agreement and this Supplement, this Supplement is controlling.

In addition to the provisions of the Loan and Security Agreement, the parties agree as follows:

Part 1 - Additional Definitions:

"Amortization Period" means the period commencing on the first day of the first full calendar month following the Interest-only Period and continuing until the Maturity Date.

"ATM Issuance" means an issuance by Borrower of its equity securities from time to time pursuant to the Sales Agreement, dated December 14, 2021, by and between Borrower and SVB Securities LLC, or any similar at-the-market offering facility that may be established in the future.

"Commitment" means, subject to the terms and conditions set forth in the Loan and Security Agreement and this Supplement, Lender's commitment to make Growth Capital Loans to Borrower in the original principal amount of Ten Million Dollars ($10,000,000), with Four Million Dollars ($4,000,000.00) funded by Avenue and Six Million Dollars ($6,000,000.00) funded by Avenue 2 on the Closing Date ("Tranche 1"); and up to Five Million Dollars ($5,000,000) to be funded between April 1, 2023 and July 31, 2023, subject to the conditions in Section 1(a)(i) of Part 2 ("Tranche 2").

"Designated Rate" means, for each Growth Capital Loan, a variable rate of interest per annum equal to the greater of (A) seven percent (7.00%) and (B) the Prime Rate, plus four and forty-five tenths of one percent (4.45%). Changes to the Designated Rate based on changes to the Prime Rate shall be effective as of the next scheduled interest payment date immediately following such change.

"Final Payment" means a payment (in addition to and not a substitution for the regular monthly payments of principal plus accrued interest) equal to four and one-quarter percent (4.25%) of the Growth Capital Loans funded.

"Growth Capital Loan" means any Loan requested by Borrower and funded by Lender under its Commitment for general corporate purposes of Borrower.

"Interest-only Period" means the period commencing on the Closing Date and continuing until the twelfth (12th) month anniversary of the Closing Date; provided, however, that such period shall be extended for an additional six (6) months if as of the last day of the Interest-only Period then in effect the Borrower has requested and Lender has funded the full amount of Tranche 2; provided, however, that the Interest-only Period shall not exceed eighteen (18) months.

"Loan" or **"Loans"** mean, as the context may require, individually a Growth Capital Loan, and collectively, the Growth Capital Loans.

"Loan Commencement Date" means, with respect to each Growth Capital Loan: (a) the first day of the first full calendar month following the Borrowing Date of such Loan if such Borrowing Date is not the first day of a month; or (b) the same day as the Borrowing Date if the Borrowing Date is the first day of a month.

"Market Price" means the lower of (i) $1.78 or (ii) the effective price of any bona fide equity financing (other than an ATM Issuance) occurring after the Date of Issuance and before June 30, 2023.

"Maturity Date" means November 1, 2025.

"Prepayment Fee" means, with respect to any prepayment of the Loans:

(i) if the prepayment occurs during the period commencing on the Closing Date and ending on (but including) the one-year anniversary of the Closing Date, an amount equal to the principal amount of the Loans prepaid multiplied by 3.00%;

(ii) if the prepayment occurs during the period commencing on the day immediately following the one-year anniversary of the Closing Date and ending on (but including) the two-year anniversary of the Closing Date, an amount equal to the principal amount of the Loans prepaid multiplied by 2.00%; and

(iii) if the prepayment occurs during the period commencing on the date immediately following the two-year anniversary of the Closing Date and ending on (but excluding) the three-year anniversary of the Closing Date, an amount equal to the principal amount of the Loans prepaid multiplied by 1.00%;

provided that, no Prepayment Fee shall be payable in connection with any refinancing of the Loans in which Agent or any Lender participates as a lender or agent.

"Prime Rate" is the rate of interest per annum from time to time published in the money rates section of The Wall Street Journal or any successor publication thereto as the "prime rate" then in effect; provided that, in the event such rate of interest is less than zero, such rate shall be deemed to be zero for purposes of this Supplement; and provided further that if such rate of interest, as set forth from time to time in the money rates section of The Wall Street Journal, becomes unavailable for any reason as determined by Lender, the "Prime Rate" shall mean the rate of interest per annum announced by Silicon Valley Bank as its prime rate in effect at its principal office in the State of California (such announced Prime Rate not being intended to be the lowest rate of interest charged by such institution in connection with extensions of credit to debtors); provided that, in the event such rate of interest is less than zero, such rate shall be deemed to be zero for purposes of this Supplement.

"Termination Date" means July 31, 2023.

"Threshold Amount" means Two Hundred Fifty Thousand Dollars ($250,000).

Part 2 - Additional Covenants and Conditions:

1. Growth Capital Loan Facility.

(a) Additional Condition Precedent Regarding Growth Capital Loan Commitments. In addition to the satisfaction of all of the other applicable conditions precedent specified in Sections 4.1 and 4.2 of the Loan and Security Agreement and this Supplement, each Lender's obligation to fund Tranche 2 of its Commitment of Growth Capital Loans is subject to receipt by Lenders of reasonably satisfactory evidence that the FDA has granted approval of the Mydcombi NDA.

(b) Minimum Funding Amount; Maximum Number of Borrowing Requests. Growth Capital Loans requested by Borrower to be made on a single Business Day shall be for a minimum aggregate, original principal amount of Two Million Five Hundred Thousand Dollars ($2,500,000); provided, however, that the initial Growth Capital Loan shall be funded on the Closing Date in the aggregate original principal amount of Ten Million Dollars ($10,000,000). Borrower shall not submit a Borrowing Request more frequently than once per calendar month.

(c) Repayment of Growth Capital Loans. Principal of, and interest on, each Growth Capital Loan shall be payable as set forth in a Note evidencing such Growth Capital Loan (substantially in the form attached hereto as Exhibit "A"), which Note shall provide substantially as follows: principal shall be fully amortized over the Amortization Period in equal, monthly principal installments plus, in each case, unpaid interest thereon at the Designated Rate, commencing after the Interest-only Period of interest-only installments at the Designated Rate. In particular, on the Borrowing Date applicable to such Growth Capital Loan, Borrower shall pay to Agent (i) if the Borrowing Date is earlier than the Loan Commencement Date, interest only at the Designated Rate, in advance, on the outstanding principal balance of the Growth Capital Loan for the period from the Borrowing Date through the last day of the calendar month in which such Borrowing Date occurs (it being understood that this clause (i) shall not apply in the case the Borrowing Date is on the same date as the Loan Commencement Date), and (ii) the first (1st) interest-only installment at the Designated Rate, in advance, on the outstanding principal balance of the Note evidencing such Loan for the ensuing month. Commencing on the first day of the second full month after the Borrowing Date and continuing on the first day of each month during the Interest-only Period thereafter, Borrower shall pay to Agent interest only at the Designated Rate, in advance, on the outstanding principal balance of the Loan evidenced by such Note for the ensuing month. Commencing on the first day of the first full month after the end of the Interest-only Period, and continuing on the first day of each consecutive calendar month thereafter, Borrower shall pay to Agent equal consecutive monthly principal installments in advance in an amount sufficient to fully amortize the Loan evidenced by such Note over the Amortization Period, plus interest at the Designated Rate for such month. On the Maturity Date, all principal and accrued interest then remaining unpaid and the Final Payment shall be due and payable.

2. Prepayment. The Growth Capital Loans may be prepaid as provided in this Section 2 only. Borrower may prepay all, but not less than all, outstanding Growth Capital Loans in whole, but not in part, at any time upon no less than five (5) Business Days' prior written notice to Lenders, by tendering to each Lender a cash payment in respect of such Loans in an amount determined by Lender equal to the sum of: (i) the aggregate outstanding principal amount of such Loans; (ii) the accrued and unpaid interest on such Loans as of the date of prepayment; (iii) the Prepayment Fee; and (iv) the Final Payment; provided that, if Lender has not yet exercised its rights under Section 3(c) hereof, Borrower shall provide written notice of prepayment at least five (5) Business Days in advance of the proposed prepayment date and Lender shall have the option, with respect to the Conversion Right, to exercise its rights pursuant to Section 3(c) hereof by delivering written notice to Borrower at least two (2) Business Days in advance of the proposed prepayment date.

3. Grant of Equity and Right to Invest; Conversion Right.

(a) Grant of Equity. As additional consideration for the making of its Commitment, the Lenders have earned and are entitled to receive immediately upon the execution of the Loan and Security Agreement and this Supplement, fully paid and nonassessable shares of Borrower's common stock (the "Common Stock") equal to 547,807 in the aggregate (the **"**Equity Grant").

(b) Equity Grant. The documents prepared by Borrower evidencing the Equity Grant shall be in form and substance reasonably satisfactory to Agent and Lenders.

(c) Right to Invest. Each Lender shall have the right, in its discretion, but not the obligation, prior to the date that is 18 months following the Closing Date (the "End Date"), to invest up to One Million Dollars ($1,000,000), in the aggregate for all such investments by Lenders pursuant to this Section 3(c), in equity securities of Borrower on the same terms, conditions, and pricing offered by Borrower to other investors in connection with any offering of Borrower's equity securities to third party investors for capital raising purposes occurring after the Closing Date and prior to the End Date; provided, however, such terms shall not include a seat on the Borrower's Board of Directors, which may be offered to other investors at Borrower's discretion. This right to invest pursuant to this Section 3(c) shall immediately terminate upon the earlier of (i) repayment of Indebtedness under the Loan and Security Agreement, (ii) the date on which an aggregate total of $1,000,000 has been invested by Lenders pursuant to this Section 3(c), and (iii) the End Date. For the avoidance of doubt, this investment right shall not apply to an ATM Issuance.

(d) Conversion Right. The Lenders shall have the right, in their discretion, but not the obligation, at any time and from time to time, while the Loans are outstanding, to convert an aggregate amount of up to Five Million Dollars ($5,000,000) of the aggregate principal amount of the outstanding Growth Capital Loans (the "Conversion Option") into Borrower's unrestricted, freely tradeable common stock (the "Conversion Right Common Stock") at a price per share equal to one hundred twenty percent (120.00%) of the closing price of Borrower's common stock on the Closing Date (the "Conversion Price"; the exercise of such Conversion Option, a "Conversion"). The Conversion Option will be exercised by Lender delivering a written, signed conversion notice to the Borrower in accordance with this Section 3(d) which will include (i) the date on which the conversion notice is given, (ii) a statement to the effect that the Lender is exercising the Conversion Option, (iii) the amount in respect of which the Conversion Option is being exercised and the number of shares to be issued and (iv) a date on which the allotment and issuance of the shares is to take place (which shall be at least two (2) Business Days prior to the date on which such notice is given).

4. Portfolio Management Fee. Borrower shall pay to each Lender pro rata in accordance with each Lender's respective commitment, a portfolio management fee in the amount of one percent (1.00%) of the total Commitment, due and payable on December 1, 2022. The Fifty Thousand Dollars ($50,000) good faith deposit that has been paid by Borrower to Lender as an advance deposit prior to the date hereof will be refunded to Borrower on the Closing Date. As an additional condition precedent under Section 4.1 of the Loan and Security Agreement, Lender shall have completed to its satisfaction its due diligence review of Borrower's business and financial condition and prospects, and each Lender's pro rata share of the Commitment shall have been approved. If this condition is not satisfied, the Fifty Thousand Dollars ($50,000) advance deposit previously paid by Borrower shall be refunded. Except as set forth in this Section 4, the Portfolio Management Fee is not refundable.

5. Documentation Fee Payment. On the Closing Date, Borrower shall reimburse each Lender and Agent pursuant to Section 9.8(a) of the Loan and Security Agreement for (i) its reasonable and documented out-of-pocket attorneys' fees, costs and expenses incurred in connection with the preparation and negotiation of the Loan Documents and (ii) each Lender's and Agent's reasonable and documented out-of-pocket costs and filing fees related to perfection of its Liens in the Collateral in any jurisdiction in which the same is located, recording a copy of the Intellectual Property Security Agreement with the United States Patent and Trademark Office or the United States Copyright Office, as applicable, and confirming the priority of such Liens.

6. Borrower's Primary Operating Account and Wire Transfer Instructions:

Institution Name:	[***]
Address:	[***]
ABA No.:	[***]
Account Title:	[***]
Account No.:	[***]

7. Debits to Account for ACH Transfers. For purposes of Sections 2.2 and 5.10 of the Loan and Security Agreement, the Primary Operating Account shall be the bank account set forth in Section 6 above, unless and until such account is changed in accordance with Section 5.10 of the Loan and Security Agreement. Borrower hereby agrees that the Growth Capital Loans will be advanced to the account specified above and regularly scheduled payments of principal, interest and fees due to each Lender will be automatically debited by each Lender from the same account. Borrower hereby confirms that the bank at which the Primary Operating Account is maintained uses that same ABA Number for incoming wires transfers to the Primary Operating Account and outgoing ACH transfers from the Primary Operating Account.

8. [Reserved].

Part 3 - Additional Representations:

Borrower represents and warrants that as of the Closing Date and, subject to any written updates of the information set forth below by Borrower to each Lender and Agent, each Borrowing Date:

a) Its chief executive office is located at: 23461 South Pointe #390, Laguna Hills, CA 92653

b) Its Equipment is located at:

295 Madison Avenue, Suite 2400 New York, NY 10017
8748 Technology Way, Suite 202, Reno, NV 89521
23461 South Pointe #390, Laguna Hills CA 92653
3503, 3505 & 3517 Haven Ave., Redwood City, CA 94063
9736 S. Virginia F-G, Reno, NV 89511

c) Its Inventory is located at: See Part 3(b) above.

d) Its Records are located at: 295 Madison Avenue, Suite 2400, New York, NY 10017

e) In addition to its chief executive office, Borrower maintains offices or operates its business at the following locations:

295 Madison Avenue, Suite 2400 New York, NY 10017
3503, 3505 & 3517 Haven Ave., Redwood City, CA 94063
8748 Technology Way, Suite 202, Reno, NV 89521
9736 S. Virginia F-G, Reno, NV 89511

f) Other than its full corporate name, Borrower has conducted business using the following trade names or fictitious business names: None.

g) Its state corporation identification number is: 5573930

h) Its U.S. federal tax identification number is: 47-1178401

i) Including Borrower's Primary Operating Account identified in Section 6 above, Borrower maintains the following Deposit Accounts and investment accounts:

Institution Name:	[***]
Address:	[***]
Account No.:	[***]
Account No.:	[***]
Account No.:	[***]

Part 4 - Additional Loan Documents:

Form of Promissory Note	Exhibit “A”
Form of Borrowing Request	Exhibit “B”
Form of Compliance Certificate	Exhibit “C”

[*Remainder of this page intentionally left blank; signature page follows*]

IN WITNESS WHEREOF, the parties have executed this Supplement as of the date first above written.

BORROWER:

EYENOVIA, INC.

By: /s/ John Gandolfo
Name: John P. Gandolfo
Title: Chief Financial Officer

Address for Notices:

23461 South Pointe #390
Laguna Hills CA 92653
Attn: Chief Financial Officer
Email:
Phone # ___-___-___

AGENT:

AVENUE CAPITAL MANAGEMENT II, L.P.

By: Avenue Capital Management II GenPar, LLC
Its: General Partner

By: /s/ Sonia Gardner
Name: Sonia Gardner
Title: Member

Address for Notices:

11 West 42nd Street, 9th Floor
New York, New York 10036
Attn: Todd Greenbarg, Senior Managing Director
Email: tgreenbarg@avenuecapital.com
Phone # 212-878-3523

LENDERS:

AVENUE VENTURE OPPORTUNITIES FUND, L.P.

By: Avenue Venture Opportunities Partners, LLC
Its: General Partner

By: /s/ Sonia Gardner
Name: Sonia Gardner
Title: Authorized Signatory

Address for Notices:

11 West 42nd Street, 9th Floor
New York, New York 10036
Attn: Todd Greenbarg, Senior Managing Director
Email: tgreenbarg@avenuecapital.com
Phone # 212-878-3523

AVENUE VENTURE OPPORTUNITIES FUND II, L.P.

By: Avenue Venture Opportunities Partners II, LLC
Its: General Partner

By: /s/ Sonia Gardner
Name: Sonia Gardner
Title: Authorized Signatory

Address for Notices:

11 West 42nd Street, 9th Floor
New York, New York 10036
Attn: Todd Greenbarg, Senior Managing Director
Email: tgreenbarg@avenuecapital.com
Phone # 212-878-3523

EXHIBIT "A"

FORM OF PROMISSORY NOTE

Note No. X-XXX

$_____ [DATE]

The undersigned ("Borrower") promises to pay to the order of [AVENUE VENTURE OPPORTUNITIES FUND, L.P., a Delaware limited partnership] [AVENUE VENTURE OPPORTUNITIES FUND II, L.P., a Delaware limited partnership] ("Lender"), at such place as Lender may designate in writing, in lawful money of the United States of America, the principal sum of _____ Dollars ($_____), with interest thereon from the date hereof until maturity, whether scheduled or accelerated, at a variable rate per annum equal to the greater of (A) seven percent (7.00%) and (B) the Prime Rate, plus four and forty-five tenths of one percent (4.45%) (the "Designated Rate"), according to the payment schedule described herein, except as otherwise provided herein. In addition, on the Maturity Date, the Borrower promises to pay to the order of Lender (i) all principal and accrued interest then remaining unpaid and (ii) the Final Payment (as defined in the Loan Agreement (as defined herein)).

This Note is one of the Notes referred to in, and is entitled to all the benefits of, a Loan and Security Agreement, dated as of November 22, 2022, between Borrower and Lender (as the same has been and may be amended, restated, amended and restated, supplemented or otherwise modified from time to time, the "Loan Agreement"). Each capitalized term not otherwise defined herein shall have the meaning set forth in the Loan Agreement. The Loan Agreement contains provisions for the acceleration of the maturity of this Note upon the happening of certain stated events.

Principal of and interest on this Note shall be payable as provided under Section 1(c) of Part 2 of the Supplement to the Loan Agreement.

This Note may be prepaid only as permitted under Section 2 of Part 2 of the Supplement to the Loan Agreement.

Any unpaid payments of principal or interest on this Note shall bear interest from their respective maturities, whether scheduled or accelerated, at a rate per annum equal to the Default Rate, compounded monthly. Borrower shall pay such interest on written demand (electronic mail being sufficient).

Interest, charges and fees shall be calculated for actual days elapsed on the basis of a 360-day year, which results in higher interest, charge or fee payments than if a 365-day year were used. In no event shall Borrower be obligated to pay interest, charges or fees at a rate in excess of the highest rate permitted by applicable law from time to time in effect.

If Borrower is late in making any scheduled payment under this Note by more than five (5) days, Borrower agrees to pay a "late charge" of five percent (5%) of the installment due, but not less than fifty dollars ($50) for any one such delinquent payment. This late charge may be charged by Lender for the purpose of defraying the expenses incidental to the handling of such delinquent amounts. Borrower acknowledges that such late charge represents a reasonable sum considering all of the circumstances existing on the date of this Note and represents a fair and reasonable estimate of the costs that will be sustained by Lender due to the failure of Borrower to make timely payments. Borrower further agrees that proof of actual damages would be costly and inconvenient. Such late charge shall be paid without prejudice to the right of Lender to collect any other amounts provided to be paid or to declare a default under this Note or any of the other Loan Documents or from exercising any other rights and remedies of Lender.

This Note shall be governed by, and construed in accordance with, the laws of the State of California, excluding those laws that direct the application of the laws of another jurisdiction.

Borrower's execution and delivery of this Note via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com) shall constitute effective execution and delivery of this Note and agreement to and acceptance of the terms hereof for all purposes. The fact that this Note is executed, signed, stored or delivered electronically shall not prevent the assignment or transfer by Lender of this Note pursuant to the terms of the Loan Agreement or the enforcement of the terms hereof. Physical possession of the original of this Note or any paper copy thereof shall confer no special status to the bearer thereof. In no event shall an original ink-signed paper copy of this Note be required for any exercise of Lender's rights hereunder.

EYENOVIA, INC.

By: _____
Name: John P. Gandolfo
Its: Chief Financial Officer

EXHIBIT "B"

FORM OF BORROWING REQUEST

Avenue Venture Opportunities Fund, L.P.
11 West 42nd Street, 9th Floor
New York, New York 10036

Avenue Venture Opportunities Fund II, L.P.
11 West 42nd Street, 9th Floor
New York, New York 10036

Re: EYENOVIA, INC.

Ladies and Gentlemen:

Reference is made to the Loan and Security Agreement, dated as of November 22, 2022 (as amended, restated, amended and restated, supplemented or otherwise modified or supplemented from time to time, the "Loan Agreement"; the capitalized terms used herein as defined therein), among Avenue Capital Management II, L.P. ("Agent"), as administrative agent and collateral agent (in such capacity, "Agent"), Avenue Venture Opportunities Fund, L.P., as a lender ("Avenue"), Avenue Venture Opportunities Fund II, L.P. ("Avenue 2" and together with Avenue, collectively, "Lenders", and each a "Lender") and Eyenovia, Inc. ("Borrower").

The undersigned is the Chief Financial Officer of Borrower and hereby requests on behalf of Borrower a Loan under the Loan Agreement, and in that connection certifies as follows:

The amount of the proposed Loan is _____ Dollars ($_____). The Borrowing Date of the proposed Loan is _____ (the "Borrowing Date").

(a) On the Borrowing Date,

(i) Avenue will wire $[_____] less fees and expenses to be deducted on the Borrowing Date of [(a) [$___] in respect to the Commitment Fee, of which $__ has been paid to Avenue prior to the date hereof, (b)][1] $[_____] in respect to the interest fee[, and (c) $[_____] in respect to the legal fees for net proceeds of $[_____]][2], and

(ii) Avenue 2 will wire $[_____] less fees and expenses to be deducted on the Borrowing Date of [(a) [$___] in respect to the Commitment Fee, of which [$___] has been paid to Avenue 2 prior to the date hereof, (b)][3] $[_____] in respect to the interest fee[, and (c) $[_____] in respect to the legal fees for net proceeds of $[_____]][4],

to Borrower pursuant to the following wire instructions:

1 To be included in the Borrowing Request on the Closing Date.
2 To be included in the Borrowing Request on the Closing Date.
3 To be included in the Borrowing Request on the Closing Date.
4 To be included in the Borrowing Request on the Closing Date.

Institution Name:	[***]
Address:	[***]
ABA No.:	[***]
Contact Name:	[***]
Phone No.:	[***]
E-mail:	[***]
Account Title:	[***]
Account No.:	[***]

[(b) On the Borrowing Date, i) Avenue will wire $[_____], and (ii) Avenue 2 will wire $[_____] to Barnes & Thornburg LLP for fees and expenses pursuant to the following wire instructions:][5]

Institution Name:	[***]
ABA No.:	[***]
Account Title:	[***]
Account No.:	[***]
Reference:	[***]
Confirm remittance:	[***]

2. As of this date, no Default or Event of Default has occurred and is continuing, or will result from the making of the proposed Loan, the representations and warranties of Borrower contained in Article 3 of the Loan Agreement and Part 3 of the Supplement are true and correct in all material respects other than those representations and warranties expressly referring to a specific date which are true and correct in all material respects as of such date, and the conditions precedent described in Sections 4.1 and/or 4.2 of the Loan Agreement and Part 2 of the Supplement, as applicable, have been met.

3. No event has occurred that has had or could reasonably be expected to have a Material Adverse Change since December 31, 2021.

4. Borrower's most recent financial statements, financial projections or business plan dated _____, as reviewed by Borrower's Board of Directors, are enclosed herewith in the event such financial statements, financial projections or business plan have not been previously provided to Agent.

Remainder of this page intentionally left blank; signature page follows

[5] To be included in the Borrowing Request on the Closing Date. The executed Borrowing Request must be delivered 2 Business Days prior to the Closing Date.

Borrower shall notify you promptly before the funding of the Loan if any of the matters to which I have certified above shall not be true and correct on the Borrowing Date.

Very truly yours,

EYENOVIA, INC.

By: _____
Name: John P. Gandolfo
Title: * Chief Financial Officer

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* Must be executed by Borrower's Chief Financial Officer or other executive officer.

EXHIBIT "C"

FORM OF
COMPLIANCE CERTIFICATE

Avenue Venture Opportunities Fund, L.P.
11 West 42nd Street, 9th Floor
New York, New York 10036

Avenue Venture Opportunities Fund II, L.P.
11 West 42nd Street, 9th Floor
New York, New York 10036

Re: EYENOVIA, INC.

Ladies and Gentlemen:

Reference is made to the Loan and Security Agreement, dated as of November __, 2022 (as the same has been and may be supplemented, amended and modified from time to time, the "Loan Agreement," the capitalized terms used herein as defined therein), among Avenue Capital Management II, L.P. ("Agent"), as administrative agent and collateral agent (in such capacity, "Agent"), Avenue Venture Opportunities Fund, L.P., as a lender ("Avenue"), Avenue Venture Opportunities Fund II, L.P. ("Avenue 2" and together with Avenue, collectively, "Lenders", and each a "Lender") and Eyenovia, Inc. ("Borrower").

The undersigned authorized representative of Borrower hereby certifies in such capacity that in accordance with the terms and conditions of the Loan Agreement, (i) no Default or Event of Default has occurred and is continuing, except as noted below, and (ii) Borrower is in compliance for the financial reporting period ending _____ with all required financial reporting under the Loan Agreement, except as noted below. Attached herewith are the required documents supporting the foregoing certification. The undersigned authorized representative of Borrower further certifies in such capacity that: (a) the accompanying financial statements have been prepared in accordance with Borrower's past practices applied on a consistent basis, or in such manner as otherwise disclosed in writing to Agent, throughout the periods indicated; and (b) the financial statements fairly present in all material respects the financial condition and operating results of Borrower and its Subsidiaries, if any, as of the dates, and for the periods, indicated therein, subject to the absence of footnotes and normal year-end audit adjustments (in the case of interim monthly financial statements), except as explained below.

Please provide the following requested information and
indicate compliance status by circling (or otherwise indicating) Yes/No under "Included/Complies":

REPORTING REQUIREMENT	REQUIRED	INCLUDED/COMPLIES
Balance Sheet, Income Statement & Cash Flow Statement	Monthly, within 30 days	YES / NO / N/A
Operating Budgets, 409(A) Valuations & Updated Capitalization Tables	As modified	YES / NO / N/A
Annual Financial Statements	Annually, within 180 day of fiscal year-end	YES / NO / N/A
Board Packages	As modified	YES / NO / N/A
Date of most recent Board-approved budget/plan _____		

Any change in budget/plan since version most recently delivered to Lender YES / NO / N/A
If Yes, please attach

Date of most recent capitalization table: _____

Any changes in capitalization table since version most recently delivered to Lender?: YES / NO / N/A
If Yes, please attach a copy of latest capitalization table

EQUITY & CONVERTIBLE NOTE FINANCINGS

Please provide the following information (if applicable) regarding Borrower's most-recent equity and/or convertible note financing each time this Certificate is delivered to Lender

Date of Last Round Raised: _____
Has there been any new financing since the last Compliance Certificate submitted? YES / NO
If "YES" please attach a copy of the Capitalization Table

Date Closed: _____ Series: _____Per Share Price: $_____
Amount Raised: _____ Post Money Valuation: _____

Any stock splits since date of last report? YES / NO
If yes, please provide any information on stock splits which would affect valuation:

Any dividends since date of last report? YES / NO
If yes, please provide any information on dividends which would affect valuation:

Any unusual terms? (i.e., Anti-dilution, multiple preference, etc.) YES / NO
If yes, please explain:

ACCOUNT CONTROL AGREEMENTS

Pursuant to Section 6.11 of the Loan Agreement, Borrower represents and warrants that: (i) as of the date hereof, it maintains only those deposit and investment accounts set forth below; and (ii) to the extent required by Section 6.11 of the Loan Agreement, a control agreement has been executed and delivered to Lender with respect to each such account ***[Note: If Borrower has established any new account(s) since the date of the last compliance certificate, please so indicate]***.

Deposit Accounts[6]

	Name of Institution	Account Number	Control Agt. In place?	Complies	New Account
1.)	[_____]	[_____]	YES / NO	YES / NO	YES / NO
2.)	_____	_____	YES / NO	YES / NO	YES / NO

6 Company: Please complete with existing accounts.

Investment Accounts

	Name of Institution	Account Number	Control Agt. In place?	Complies	New Account
1.)	None		YES / NO	YES / NO	YES / NO
2.)			YES / NO	YES / NO	YES / NO
3.)			YES / NO	YES / NO	YES / NO
4.)			YES / NO	YES / NO	YES / NO

AGREEMENTS WITH PERSONS IN POSSESSION OF TANGIBLE COLLATERAL

Pursuant to Section 5.9(e) of the Loan Agreement, Borrower represents and warrants that: (i) as of the date hereof, tangible Collateral is located at the addresses set forth below; and (ii) to the extent required by Section 5.9(e) of the Loan Agreement, a Waiver has been executed and delivered to Lender, or such Waiver has been waived by Lender, ***[Note: If Borrower has located Collateral at any new location since the date of the last compliance certificate, please so indicate].***

	Location of Collateral	Value of Collateral at such Locations	Waiver In place?	Complies?	New Location?
1.)		$	YES / NO	YES / NO	YES / NO
2.)		$	YES / NO	YES / NO	YES / NO
3.)		$	YES / NO	YES / NO	YES / NO
4.)		$	YES / NO	YES / NO	YES / NO

SUBSIDIARIES AND OTHER PERSONS

Pursuant to Section 6.14(a) of the Loan Agreement, Borrower represents and warrants that: (i) as of the date hereof, it has directly or indirectly acquired or created, or it intends to directly or indirectly acquire or create, each Subsidiary or other Person described below; and (ii) such Subsidiary or Person has been made a co-borrower under the Loan Agreement or a guarantor of the Obligations ***[Note: If Borrower has acquired or created any Subsidiary since the date of the last compliance certificate, please so indicate].***

	Name:	Jurisdiction of formation or organization:[7]	Co-borrower or guarantor?	Complies?	New Subsidiary or Person?
1.)			YES / NO	YES / NO	YES / NO
2.)			YES / NO	YES / NO	YES / NO
3.)			YES / NO	YES / NO	YES / NO

[7] Under the "Explanations" heading (see below) please include a description of such Subsidiary's or Person's fully diluted capitalization and Borrower's purpose for its acquisition or creation of such Subsidiary if such information has not been previously furnished to Lender.

4.)	_____	_____	YES / NO	YES / NO	YES / NO

EXPLANATIONS

_____

_____

_____

_____

[*Remainder of this page intentionally left blank; signature page follows*]

Very truly yours,

EYENOVIA, INC.

By: _____
Name: _____
Title: * _____

* Must be executed by Borrower's Chief Financial Officer or other executive officer.

Exhibit 10.32

SUBSCRIPTION AGREEMENT

Eyenovia, Inc.
295 Madison Avenue, Suite 2400
New York, NY 10017

Ladies and Gentlemen:

This Subscription Agreement (this "Subscription Agreement") is being entered into as of the date set forth on the signature page hereto, by and among Eyenovia, Inc., a Delaware corporation (the "Company"), Avenue Venture Opportunities Fund, L.P. ("Avenue") and Avenue Venture Opportunities Fund II, L.P. ("Avenue 2," and together with Avenue, each an "Investor" and collectively, the "Investors").

This Subscription Agreement is entered into in connection with that certain Loan and Security Agreement by and among the Company, Avenue Capital Management II, L.P. (the "Agent") and the Investors, dated as of even date herewith, as supplemented by the Supplement to the Loan and Security Agreement, by and among the Company, the Agent and the Investors (collectively, the "LSA").

In connection therewith, and in consideration of the foregoing and the mutual representations, warranties and covenants, and subject to the conditions, set forth herein, and intending to be legally bound hereby, each of the Investors and the Company acknowledges and agrees as follows:

1. Subscription. Investor hereby irrevocably subscribes for the number of shares of common stock, par value $0.0001 per share, of the Company set forth on the signature page of this Subscription Agreement (the "Shares") on the terms and subject to the conditions provided for herein.

2. Closing. The closing of the issuance of the Shares (the "Closing") shall occur substantially concurrently with and conditioned upon the execution of the LSA (as defined above) (the "Closing Date"). On the Closing Date, the Company shall issue the number of Shares to Investor set forth on the signature page to this Subscription Agreement, and shall subsequently cause such Shares to be registered in book entry form in the name of Investor on the Company's share register. For purposes of this Subscription Agreement, "business day" shall mean a day, other than a Saturday or Sunday, on which commercial banks in New York, New York are open for the general transaction of business.

3. Closing Conditions.

(a) The obligation of the parties hereto to consummate the issuance of the Shares pursuant to this Subscription Agreement is subject to the following conditions:

(i) the execution of the LSA;

(ii) no applicable governmental authority shall have enacted, issued, promulgated, enforced or entered any judgment, order, law, rule or regulation

(whether temporary, preliminary or permanent) which is then in effect and has the effect of making consummation of the transactions contemplated hereby illegal or otherwise restraining or prohibiting consummation of the transactions contemplated hereby; and

(iii) all conditions precedent to the closing of the Transaction shall have been satisfied or waived (as determined by the parties thereto and other than those conditions which, by their nature, are to be fulfilled at the closing of the Transaction, including to the extent that any such condition is dependent upon the consummation of the issuance of the Shares pursuant to this Subscription Agreement).

(b) The obligation of the Company to consummate the issuance and sale of the Shares pursuant to this Subscription Agreement shall be subject to the condition that all representations and warranties of Investor contained in this Subscription Agreement are true and correct in all material respects (other than representations and warranties that are qualified as to materiality or Material Adverse Effect, which representations and warranties shall be true in all respects) at and as of the Closing Date, and consummation of the Closing shall constitute a reaffirmation by Investor of each of the representations and warranties of Investor contained in this Subscription Agreement as of the Closing Date.

(c) The obligation of Investor to consummate the purchase of the Shares pursuant to this Subscription Agreement shall be subject to the condition that all representations and warranties of the Company contained in this Subscription Agreement shall be true and correct in all material respects (other than representations and warranties that are qualified as to materiality or Material Adverse Effect (as defined herein), which representations and warranties shall be true in all respects) at and as of the Closing Date, and consummation of the Closing shall constitute a reaffirmation by the Company of each of the representations and warranties of the Company contained in this Subscription Agreement as of the Closing Date.

4. Further Assurances. The parties hereto shall execute and deliver such additional documents and take such additional actions as the parties reasonably may deem to be practical and necessary in order to consummate the subscription as contemplated by this Subscription Agreement.

5. Company Representations and Warranties. The Company represents and warrants to Investor that:

(a) The Company is a corporation duly incorporated, validly existing and in good standing under the laws of the State of Delaware. The Company has all corporate power and authority to own, lease and operate its properties and conduct its business as presently conducted and to enter into, deliver and perform its obligations under this Subscription Agreement.

(b) As of the Closing Date, the Shares will be duly authorized and, when issued and delivered to Investor in accordance with the terms of this Subscription Agreement and the LSA, the Shares will be validly issued, fully paid and non-assessable and will not have been

issued in violation of or subject to any preemptive or similar rights created under the Company's certificate of incorporation (as amended to the Closing Date) or under the General Corporation Law of the State of Delaware.

(c) This Subscription Agreement has been duly authorized, executed and delivered by the Company and, assuming that this Subscription Agreement constitutes the valid and binding agreement of Investor, this Subscription Agreement is enforceable against the Company in accordance with its terms, except as may be limited or otherwise affected by (i) bankruptcy, insolvency, fraudulent conveyance, reorganization, moratorium or other laws relating to or affecting the rights of creditors generally, or (ii) principles of equity, whether considered at law or equity.

(d) The issuance and sale of the Shares and the compliance by the Company with all of the provisions of this Subscription Agreement and the consummation of the transactions contemplated herein will not conflict with or result in a breach or violation of any of the terms or provisions of, or constitute a default under, or result in the creation or imposition of any lien, charge or encumbrance upon any of the property or assets of the Company pursuant to the terms of (i) any indenture, mortgage, deed of trust, loan agreement, lease, license or other agreement or instrument to which the Company is a party or by which the Company is bound or to which any of the property or assets of the Company is subject that would reasonably be expected to have a material adverse effect on the business, financial condition or results of operations of the Company, taken as a whole (a "Material Adverse Effect") or materially affect the validity of the Shares or the legal authority of the Company to comply in all material respects with the terms of this Subscription Agreement; (ii) result in any violation of the provisions of the organizational documents of the Company; or (iii) result in any violation of any statute or any judgment, order, rule or regulation of any court or governmental agency or body, domestic or foreign, having jurisdiction over the Company or any of their properties that would reasonably be expected to have a Material Adverse Effect or materially affect the validity of the Shares or the legal authority of the Company to comply in all material respects with this Subscription Agreement.

6. Investor Representations and Warranties. Investor represents and warrants to the Company that:

(a) Investor (i) is a "qualified institutional buyer" (as defined in Rule 144A under the Securities Act of 1933, as amended (the "Securities Act")) or an institutional "accredited investor" (within the meaning of Rule 501(a) under the Securities Act), in each case, satisfying the applicable requirements set forth on Schedule A, (ii) is acquiring the Shares only forits own account and not for the account of others, and (iii) is not acquiring the Shares with a view to, or for offer or sale in connection with, any distribution thereof in violation of the Securities Act (and shall provide the requested information set forth on Schedule A). Investor is not an entity formed for the specific purpose of acquiring the Shares and is an "institutional account" as defined by FINRA Rule 4512(c).

(b) Investor acknowledges and agrees that the Shares are being offered in a transaction not involving any public offering within the meaning of the Securities Act and that the Shares have not been registered under the Securities Act. Investor acknowledges and agrees

that the Shares may not be offered, resold, transferred, pledged or otherwise disposed of by Investor absent an effective registration statement under the Securities Act except (i) to the Company or a subsidiary thereof, (ii) to non-U.S. persons pursuant to offers and sales that occur outside the United States within the meaning of Regulation S under the Securities Act or (iii) pursuant to another applicable exemption from the registration requirements of the Securities Act, and in each case in accordance with any applicable securities laws of the states of the United States and other jurisdictions, and that any certificates representing the Shares shall contain a restrictive legend to such effect. Investor acknowledges and agrees that the Shares will be subject to transfer restrictions and, as a result of these transfer restrictions, Investor may not be able to readily offer, resell, transfer, pledge or otherwise dispose of the Shares and may be required to bear the financial risk of an investment in the Shares for an indefinite period of time. Investor acknowledges and agrees that the Shares will not be eligible for offer, resale, transfer, pledge or disposition pursuant to Rule 144 promulgated under the Securities Act until at least six months from the Closing Date. Investor acknowledges and agrees that it has been advised to consult legal counsel prior to making any offer, resale, transfer, pledge or disposition of any of the Shares.

(c) Investor acknowledges that there have been no representations, warranties, covenants and agreements made to Investor by or on behalf of the Company, any of its affiliates or any control persons, officers, directors, employees, partners, agents or representatives of any of the foregoing or any other person or entity, expressly or by implication, other than those representations, warranties, covenants and agreements of the Company expressly set forth in Section 5 of this Subscription Agreement.

(d) Investor's acquisition and holding of the Shares will not constitute or result in a non-exempt prohibited transaction under Section 406 of the Employee Retirement Income Security Act of 1974, as amended, Section 4975 of the Internal Revenue Code of 1986, as amended, or any applicable similar law.

(e) Investor acknowledges and agrees that Investor has received such information as Investor deems necessary in order to make an investment decision with respect to the Shares, including, with respect to the Company and its subsidiaries. Without limiting the generality of the foregoing, Investor acknowledges that it has reviewed the Company's filings with the U.S. Securities and Exchange Commission (the "SEC"). Investor acknowledges and agrees that Investor and Investor's professional advisor(s), if any, have had the full opportunity to ask such questions, receive such answers and obtain such information as Investor and such Investor's professional advisor(s), if any, have deemed necessary to make an investment decision with respect to the Shares.

(f) Investor became aware of this offering of the Shares solely by means of direct contact between Investor and the Company or a representative of the Company, and the Shares were offered to Investor solely by direct contact between Investor and the Company or a representative of the Company. Investor acknowledges that the Shares (i) were not offered by any form of general solicitation or general advertising and (ii) are not being offered in a manner involving a public offering under, or in a distribution in violation of, the Securities Act, or any state securities laws. Investor acknowledges that it is not relying upon, and has not relied upon, any statement, representation or warranty made by any person, firm or corporation (including,

without limitation, the Company, any of its affiliates or any control persons, officers, directors, employees, partners, agents or representatives of any of the foregoing), other than the representations and warranties of the Company contained in Section 5 of this Subscription Agreement, in making its investment or decision to invest in the Company.

(g) Investor acknowledges that it is aware that there are substantial risks incident to the purchase and ownership of the Shares, including those set forth in the Company's filings with the SEC. Investor has such knowledge and experience in financial and business matters as to be capable of evaluating the merits and risks of an investment in the Shares, and Investor has sought such accounting, legal and tax advice as Investor has considered necessary to make an informed investment decision. Investor is able to sustain a complete loss on its investment in the Shares, has no need for liquidity with respect to its investment in the Shares and has no reason to anticipate any change in circumstances, financial or otherwise, which may cause or require any sale or distribution of all or any part of the Shares.

(h) Alone, or together with any professional advisor(s), Investor has adequately analyzed and fully considered the risks of an investment in the Shares and determined that the Shares are a suitable investment for Investor and that Investor is able at this time and in the foreseeable future to bear the economic risk of a total loss of Investor's investment in the Company. Investor acknowledges specifically that a possibility of total loss exists.

(i) In making its decision to purchase the Shares, Investor has relied solely upon independent investigation made by Investor.

(j) Investor acknowledges and agrees that no federal or state agency has passed upon or endorsed the merits of the offering of the Shares or made any findings or determination as to the fairness of this investment.

(k) Investor has been duly formed or incorporated and is validly existing and is in good standing under the laws of its jurisdiction of formation or incorporation, with power and authority to enter into, deliver and perform its obligations under this Subscription Agreement.

(l) The execution, delivery and performance by Investor of this Subscription Agreement are within the powers of Investor, have been duly authorized and will not constitute or result in a breach or default under or conflict with any order, ruling or regulation of any court or other tribunal or of any governmental commission or agency, or any agreement or other undertaking, to which Investor is a party or by which Investor is bound, and will not violate any provisions of Investor's organizational documents, including, without limitation, its incorporation or formation papers, bylaws, indenture of trust or partnership or operating agreement, as may be applicable. The signature on this Subscription Agreement is genuine, and the signatory has legal competence and capacity to execute the same or the signatory has been duly authorized to execute the same, and this Subscription Agreement constitutes a legal, valid and binding obligation of Investor, enforceable against Investor in accordance with its terms except as may be limited or otherwise affected by (i) bankruptcy, insolvency, fraudulent conveyance, reorganization, moratorium or other laws relating to or affecting the rights of creditors generally, and (ii) principles of equity, whether considered at law or equity.

(m) Investor is not (i) a person or entity named on the List of Specially Designated Nationals and Blocked Persons administered by the U.S. Treasury Department's Office of Foreign Assets Control ("OFAC") or in any Executive Order issued by the President of the United States and administered by OFAC ("OFAC List"), or a person or entity prohibited by any OFAC sanctions program, (ii) a Designated National as defined in the Cuban Assets Control Regulations, 31 C.F.R. Part 515, or (iii) a non-U.S. shell bank or providing banking services indirectly to a non-U.S. shell bank (each, a "Prohibited Investor"). Investor agrees to provide law enforcement agencies, if requested thereby, such records as required by applicable law, provided that Investor is permitted to do so under applicable law. If Investor is a financial institution subject to the Bank Secrecy Act (31 U.S.C. Section 5311 et seq.) (the "BSA"), as amended by the USA PATRIOT Act of 2001 (the "PATRIOT Act"), and its implementing regulations (collectively, the "BSA/PATRIOT Act"), Investor maintains policies and procedures reasonably designed to comply with applicable obligations under the BSA/PATRIOT Act. To the extent required, it maintains policies and procedures reasonably designed for the screening of its investors against the OFAC sanctions programs, including the OFAC List. To the extent required by applicable law, Investor maintains policies and procedures reasonably designed to ensure that the funds held by Investor and used to purchase the Shares were legally derived and were not obtained, directly or indirectly, from a Prohibited Investor.

(n) In connection with the issue and purchase of the Shares, no person, firm or corporation has acted as Investor's financial advisor or fiduciary.

7. Termination. This Subscription Agreement shall terminate and be void and of no further force and effect, and all rights and obligations of the parties hereunder shall terminate if any of the conditions to Closing set forth in Section 3 of this Subscription Agreement are (i) not satisfied or waived prior to the Closing (and if the failure to so satisfy such condition is capable of being cured prior to the Closing, such failure shall not have been cured by the thirtieth calendar day following receipt of written notice from the party claiming such condition has not been satisfied) or (ii) not capable of being satisfied on the Closing and, in each case of (i) and (ii), as a result thereof, the transactions contemplated by this Subscription Agreement will not be and are not consummated at the Closing (collectively, the "Termination Events"); provided that nothing herein will relieve any party from liability for any willful breach hereof prior to the time of termination, and each party will be entitled to any remedies at law or in equity to recover losses, liabilities or damages arising from any such willful breach. Upon the occurrence of any Termination Event, this Subscription Agreement shall be void and of no further effect and any monies paid by Investor to the Company in connection herewith shall promptly (and in any event within one business day) following the Termination Event be returned to Investor, which obligation to return such monies and remedies for losses, liabilities and damages arising from willful breach shall survive termination of this Subscription Agreement.

8. Miscellaneous.

(a) Neither this Subscription Agreement nor any rights that may accrue to Investor hereunder (other than the Shares acquired hereunder, if any) may be transferred or assigned.

(b) Investor acknowledges that the Company may file a copy of this Subscription Agreement with the SEC as an exhibit to a periodic report or a registration statement of the Company.

(c) Investor acknowledges that the Company and others will rely on the acknowledgments, understandings, agreements, representations and warranties contained in this Subscription Agreement. Prior to the Closing, Investor agrees to promptly notify the Company if any of the acknowledgments, understandings, agreements, representations and warranties set forth in Section 6 above are no longer accurate. Investor acknowledges and agrees that each purchase by Investor of Shares from the Company will constitute a reaffirmation of the acknowledgments, understandings, agreements, representations and warranties herein (as modified by any such notice) by Investor as of the time of such purchase.

(d) The Company is entitled to rely upon this Subscription Agreement and is irrevocably authorized to produce this Subscription Agreement or a copy hereof to any interested party in any administrative or legal proceeding or official inquiry with respect to the matters covered hereby.

(e) All of the agreements, representations and warranties made by each party hereto in this Subscription Agreement shall survive the Closing.

(f) This Subscription Agreement may not be modified, waived or terminated (other than pursuant to the terms of Section 8 above) except by an instrument in writing, signed by each of the parties hereto. No failure or delay of either party in exercising any right or remedy hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such right or power, or any abandonment or discontinuance of steps to enforce such right or power, or any course of conduct, preclude any other or further exercise thereof or the exercise of any other right or power. The rights and remedies of the parties hereunder are cumulative and are not exclusive of any rights or remedies that they would otherwise have hereunder.

(g) This Subscription Agreement (including the schedule hereto) constitutes the entire agreement, and supersedes all other prior agreements, understandings, representations and warranties, both written and oral, among the parties, with respect to the subject matter hereof. Except as set forth in Section 7, Section 8(c), Section 8(d), Section 8(f), this Section 8(g), and the last sentence of Section 8(k) with respect to the persons specifically referenced therein, this Subscription Agreement shall not confer any rights or remedies upon any person other than the parties hereto, and their respective successor and assigns, and the parties hereto acknowledge that such persons so referenced are third party beneficiaries of this Subscription Agreement for the purposes of, and to the extent of, the rights granted to them, if any, pursuant to the applicable provisions.

(h) Except as otherwise provided herein, this Subscription Agreement shall be binding upon, and inure to the benefit of the parties hereto and their heirs, executors, administrators, successors, legal representatives, and permitted assigns, and the agreements, representations, warranties, covenants and acknowledgments contained herein shall be deemed to be made by, and be binding upon, such heirs, executors, administrators, successors, legal representatives and permitted assigns.

(i) If any provision of this Subscription Agreement shall be adjudicated by a court of competent jurisdiction to be invalid, illegal or unenforceable, the validity, legality or enforceability of the remaining provisions of this Subscription Agreement shall not in any way be affected or impaired thereby and shall continue in full force and effect.

(j) This Subscription Agreement may be executed in one or more counterparts (including by facsimile or electronic mail or in .pdf) and by different parties in separate counterparts, with the same effect as if all parties hereto had signed the same document. All counterparts so executed and delivered shall be construed together and shall constitute one and the same agreement.

(k) The parties hereto acknowledge and agree that irreparable damage would occur in the event that any of the provisions of this Subscription Agreement were not performed in accordance with their specific terms or were otherwise breached. It is accordingly agreed that the parties shall be entitled to an injunction or injunctions to prevent breaches of this Subscription Agreement, without posting a bond or undertaking and without proof of damages, to enforce specifically the terms and provisions of this Subscription Agreement, this being in addition to any other remedy to which such party is entitled at law, in equity, in contract, in tort or otherwise.

(l) This Subscription Agreement shall be governed by and construed in accordance with the laws of the State of Delaware (regardless of the laws that might otherwise govern under applicable principles of conflicts of laws thereof) as to all matters (including any action, suit, litigation, arbitration, mediation, claim, charge, complaint, inquiry, proceeding, hearing, audit, investigation or reviews by or before any governmental entity related hereto), including matters of validity, construction, effect, performance and remedies.

(m) Any action, suit or proceeding between or among the parties hereto, whether arising in contract, tort or otherwise, arising in connection with any disagreement, dispute, controversy or claim arising out of or relating to this Subscription Agreement or any related document or any of the transactions contemplated hereby or thereby ("Legal Dispute") shall be brought only to the exclusive jurisdiction of the courts of the State of Delaware or the federal courts located in the State of Delaware, and each party hereto hereby consents to the jurisdiction of such courts (and of the appropriate appellate courts therefrom) in any such suit, action or proceeding and irrevocably waives, to the fullest extent permitted by law, any objection that it may now or hereafter have to the laying of the venue of any such suit, action or proceeding in any such court or that any such suit, action or proceeding that is brought in any such court has been brought in an inconvenient forum. During the period a Legal Dispute that is filed in accordance with this Section 8(m) is pending before a court, all actions, suits or proceedings with respect to such Legal Dispute or any other Legal Dispute, including any counterclaim, cross-claim or interpleader, shall be subject to the exclusive jurisdiction of such court. A final judgment in any action, suit or proceeding described in this Section 8(m) following the expiration of any period permitted for appeal and subject to any stay during appeal shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by applicable laws. EACH OF THE PARTIES HERETO IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT TO TRIAL BY JURY ON ANY CLAIMS OR COUNTERCLAIMS ASSERTED IN ANY LEGAL DISPUTE RELATING TO

THIS SUBSCRIPTION AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY AND FOR ANY COUNTERCLAIM RELATING THERETO. IF THE SUBJECT MATTER OF ANY SUCH LEGAL DISPUTE IS ONE IN WHICH THE WAIVER OF JURY TRIAL IS PROHIBITED, NO PARTY HERETO NOR ANY PERSON ASSERTING RIGHTS AS A THIRD PARTY BENEFICIARY SHALL ASSERT IN SUCH LEGAL DISPUTE A NONCOMPULSORY COUNTERCLAIM ARISING OUT OF OR RELATING TO THIS SUBSCRIPTION AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY. FURTHERMORE, NO PARTY HERETO NOR ANY PERSON ASSERTING RIGHTS AS A THIRD PARTY BENEFICIARY SHALL SEEK TO CONSOLIDATE ANY SUCH LEGAL DISPUTE WITH A SEPARATE ACTION OR OTHER LEGAL PROCEEDING IN WHICH A JURY TRIAL CANNOT BE WAIVED.

[*SIGNATURE PAGE FOLLOWS*]

IN WITNESS WHEREOF, the Investor has executed or caused this Subscription Agreement to be executed by its duly authorized representative as of the date set forth below.

Name of Investor:	State/Country of Formation or Domicile:
AVENUE VENTURE OPPORTUNITIES FUND, L.P.	Delaware

By: Avenue Venture Opportunities Partners, LLC
Its: General Partner

By: /s/ Sonia Gardner
Name: Sonia Gardner
Title: Authorized Signatory
Date: November 22, 2022

Name in which Shares are to be registered
(if different):

Investor's EIN: 84-3308847

Business Address-Street: 11 West 42nd Street, 9th Floor
City, State, Zip: New York, New York 10036
Attn: Todd Greenbarg, Senior Managing Director
Telephone No.: 212-878-3523
Email: tgreenbarg@avenuecapital.com

For notices, with copy to (which shall not constitute notice):

Barnes & Thornburg LLP
655 W. Broadway, Suite 1300
San Diego, CA 92101
Attn: Troy Zander
Email: troy.zander@btlaw.com

Number of Shares: 219,123

IN WITNESS WHEREOF, the Investor has executed or caused this Subscription Agreement to be executed by its duly authorized representative as of the date set forth below.

Name of Investor:	State/Country of Formation or Domicile:
AVENUE VENTURE OPPORTUNITIES FUND II, L.P.	Delaware

By: Avenue Venture Opportunities Partners II, LLC
Its: General Partner

By: /s/ Sonia Gardner
Name: Sonia Gardner
Title: Authorized Signatory
Date: November 22, 2022

Name in which Shares are to be registered (if different):

Investor's EIN: 87-2781311

Business Address-Street: 11 West 42nd Street, 9th Floor
City, State, Zip: New York, New York 10036
Attn: Todd Greenbarg, Senior Managing Director
Telephone No.: 212-878-3523
Email: tgreenbarg@avenuecapital.com

For notices, with copy to (which shall not constitute notice):

Barnes & Thornburg LLP
655 W. Broadway, Suite 1300
San Diego, CA 92101
Attn: Troy Zander
Email: troy.zander@btlaw.com

Number of Shares: 328,684

IN WITNESS WHEREOF, the Company has accepted this Subscription Agreement as of the date set forth below.

EYENOVIA, INC.

By: /s/ John P. Gandolfo
Name: John P. Gandolfo
Title: Chief Financial Officer

Date: November 22, 2022

SCHEDULE A

ELIGIBILITY REPRESENTATIONS OF INVESTOR

A. QUALIFIED INSTITUTIONAL BUYER STATUS

(Please check the applicable subparagraphs):

☐ We are a "qualified institutional buyer" (as defined in Rule 144A under the Securities Act (a "QIB")).

B. INSTITUTIONAL ACCREDITED INVESTOR STATUS

(Please check the applicable subparagraphs):

1. ☐ We are an "accredited investor" (within the meaning of Rule 501(a) under the Securities Act or an entity in which all of the equity holders are accredited investors within the meaning of Rule 501(a) under the Securities Act), and have marked and initialed the appropriate box below indicating the provision under which we qualify as an "accredited investor."

2. ☐ We are not a natural person.

Rule 501(a), in relevant part, states that an "accredited investor" shall mean any person who comes within any of the below listed categories, or who the issuer reasonably believes comes within any of the below listed categories, at the time of the sale of the securities to that person. Investor has indicated, by marking and initialing the appropriate box below, the provision(s) below which apply to Investor and under which Investor accordingly qualifies as an "accredited investor."

☐ Any bank, registered broker or dealer, insurance company, registered investment company, business development company, or small business investment company;

☐ Any plan established and maintained by a state, its political subdivisions, or any agency or instrumentality of a state or its political subdivisions for the benefit of its employees, if such plan has total assets in excess of $5,000,000;

☐ Any employee benefit plan, within the meaning of the Employee Retirement Income Security Act of 1974, if a bank, insurance company, or registered investment adviser makes the investment decisions, or if the plan has total assets in excess of $5,000,000;

☐ Any organization described in Section 501(c)(3) of the Internal Revenue Code, corporation, similar business trust, or partnership, not formed for the specific purpose of acquiring the securities offered, with total assets in excess of $5,000,000;

☐ Any trust with assets in excess of $5,000,000, not formed for the specific purpose of acquiring the securities offered, whose purchase is directed by a sophisticated person;

☐ Any entity in which all of the equity owners are accredited investors within the meaning of Rule 501(a); or

☐ Any natural person who (i) has an individual net worth, or joint net worth with their spouse or equivalent, in excess of $1,000,000, (ii) had an individual income in excess of $200,000 in each of the two most recent years, or (iii) had joint income with their spouse or equivalent in excess of $300,000 in each of the two most recent years and has a reasonable expectation of reaching the same income level in the current year.

This page should be completed by Investor

and constitutes a part of the Subscription Agreement.

Exhibit 10.33

EMPLOYMENT AGREEMENT

This EMPLOYMENT AGREEMENT (the "***Agreement***") is entered into as of December 19, 2022, by and between **Eyenovia, Inc.**, a Delaware company (the "***Company***"*),* and Bren Kern, an individual residing in the State of Oregon ("***Executive***"). The Company and Executive are hereinafter collectively referred to as the "***Parties***," and individually a "***Party***."

AGREEMENT

1. Position, Duties, Responsibilities.

(a) Position and Location. Executive shall render services to the Company in the position of Chief Operating Officer (the "***COO***") reporting to the Chief Executive Officer (the "***CEO***") of the Company, and shall perform all services appropriate to that position for an organization the size of the Company that is engaged in the type of business engaged by the Company, as well as such other services of a nature customary to the position of COO and as may be assigned by the CEO and/or Board of Directors of the Company (the "***Board***"). Executive shall devote the Executive's best efforts to the performance of the Executive's duties and must at all times act in good faith towards the Company. Executive's office will initially be located in Reno, Nevada, but Executive shall travel, from time to time, as Company business dictates without additional remuneration but subject to the reimbursement of business expenses, as set forth in Section 3(e) below.

(b) Other Activities. Except upon the prior written consent of the CEO, Executive will not: (i) accept any other employment or engagement, (ii) engage, directly or indirectly, in any other activity (whether or not pursued for pecuniary advantage) that is or may be in conflict with, or that might place Executive in a conflicting position to that of the Company, or prevent Executive from devoting such time as necessary to fulfill the Executive's responsibilities under this Agreement, (iii) sell, market or represent any product or service other than the Company's products or services, or (iv) serve on any board of directors for any other company (other than the Company).

(c) Devotion of Time and Energies. Except as set forth in Section 1(b), Executive will devote all of the Executive's working time and attention to the performance of the Executive's duties under this Agreement.

(d) Duties and Authority. Subject to Section 1(a), Executive shall have responsibility for managing the Manufacturing, Device Research and Development, and Quality operations of the Company as directed by the CEO and/or the Board, consistent with the Executive's position as COO.

2. Term.

(a) Term. Subject to the terms hereof, Executive's employment as COO hereunder shall commence on January 1, 2023 (the "***Commencement Date***") and shall continue until terminated hereunder by either Executive or Company as described herein. Such term of employment shall be referred to herein as the "***Term***."

(b) Termination. Notwithstanding anything else contained in this Agreement, Executive's employment hereunder shall terminate upon the earliest to occur of the following:

(1) Death. In the event of Executive's death, Executive's employment shall immediately conclude.

(2) Disability. In the event of Executive's Disability (as defined in Section 2(c) below), Executive's employment shall conclude upon written notice by Company to Executive that Executive's employment is being terminated as a result of Executive's Disability, which termination shall be effective on the date of such notice or such later date as specified in writing by Company;

(3) Termination by Company.

(i) For Cause. The Company may terminate the Executive's employment under this Agreement for Cause (as defined in Section 2(d)), upon written notice by Company to Executive that Executive's employment is being terminated for Cause and that sets forth the factual basis supporting the alleged Cause, which termination shall be effective on the later of the date of such notice or such later date as specified in writing by Company; or

(ii) Without Cause. If by Company for reasons other than Disability or Cause, upon written notice by Company to Executive that Executive's employment is being terminated, which termination shall be effective on the date of such notice or such later date as specified in writing by Company.

(4) Termination by the Executive. Executive may terminate Executive's employment with the Company under the following conditions:

(i) Termination by Executive for Good Reason. If for Good Reason (as defined in Section 2(e) below), upon written notice by Executive to Company that Executive is terminating Executive's employment for Good Reason and that sets forth the factual basis supporting the alleged Good Reason, which termination shall be effective five (5) days after the date that the Company's cure period ends, as set forth in Section 2(e) below; provided that if Company has cured the circumstances giving rise to the Good Reason, then such termination shall not be effective; or

(ii) Termination by Executive without Good Reason. If without Good Reason, written notice by Executive to Company that Executive is terminating Executive's employment, which termination shall be effective at least thirty (30) days after the date of such notice; provided that the Company may accept such resignation and accelerate such termination in its discretion without payment for the remainder of such notice.

(c) Definition of Disability. "***Disability***" shall mean the inability of the Executive to perform the Executive's duties under this Agreement because the Executive has become permanently or completely disabled or otherwise eligible for long-term disability within the meaning of any policy of disability income insurance covering employees of the Company then in force. In the event the Company has no policy of disability income insurance covering employees of the Company, the term Disability shall mean the inability of the Executive to perform the Executive's duties under this Agreement by reason of any incapacity, physical or mental, which the Board, based upon medical advice or an opinion provided by a licensed physician acceptable to the Board, determines to have incapacitated the Executive from satisfactorily performing all of the Executive's usual services for the Company for a period of at least one hundred twenty (120) consecutive days during any rolling twelve (12) month period. The determination of the Board shall be final and binding and the date such determination is made shall be the date of such Disability for purposes of this Agreement.

(d) Definition of Cause. "***Cause***" shall mean: (i) Executive's engagement in illegal conduct, gross misconduct or gross negligence; (ii) Executive's insubordination with regard to a lawful and reasonable directive by the CEO and/or the Board, or material malfeasance or nonfeasance of duty with respect to his duties and responsibilities to the Company, provided that Cause shall not include nonfeasance due to Executive's Disability; (iii) Executive's embezzlement, knowing misappropriation of funds, or fraud; (iv) Executive's material breach of the Confidentiality Agreement, or similar agreement between Executive and Company; or (v) Executive's material breach of any written employment agreement between Executive and Company or violation of a material provision of any Company employment policy; provided that if the circumstance(s) in subsection (ii), (iv) or (v) is (or are) capable of being cured, Company has first provided Executive with written notice setting forth in reasonable detail the circumstance(s) that Company alleges constitute(s) "Cause" and Executive has failed to cure such circumstance(s) within a period of thirty (30) days after the date of receipt of such written notice.

(e) Definition of Good Reason. "***Good Reason***" means the existence of any one or more of the following conditions without the Executive's consent, provided Executive submits written notice to the Company within forty-five (45) days of when such condition(s) first arose specifying the condition(s): (i) a material adverse change in his title or reporting relationships; (ii) material adverse change in his position with the Company which materially reduces his authority, duties or responsibilities, or the assignment to the Executive of duties materially inconsistent with the Executive's position with the Company; (iii) a material reduction in the Executive's then current Base Salary and; (iv) a material breach by the Company of this Agreement; provided that within forty-five (45) days of the Company's act or omission giving rise to a termination for Good Reason, the Executive notifies the Company in a writing of the act or omission, the Company fails to correct the act or omission within thirty (30) days after receiving the Executive's written notice and the Executive actually terminates his employment within thirty (30) days after the date the Company receives the Executive's notice.

3. Compensation. In consideration of the services to be rendered under this Agreement, Executive shall be entitled to the following:

(a) Base Salary. The Company shall pay to Executive an initial annual salary of three hundred and forty-five thousand dollars ($345,000.00), less all applicable withholdings, which shall be payable in accordance with the Company's payroll practices (the "***Base Salary***").

(b) Annual Bonus. Executive shall be eligible to receive an annual cash bonus in a target amount initially up to thirty percent (30%) of Executive's then-current Base Salary (the "***Target Bonus***") (any such bonus, as it may be adjusted herein, the "***Annual Bonus***"). Annual performance objectives will generally be determined by the Compensation Committee by the end of the 1st quarter of each calendar year. The grant and amount of the Annual Bonus shall be determined by the Compensation Committee in its sole discretion, based on its determination of Executive's achievement of milestones for the applicable year. Any such Bonus compensation will be paid (minus applicable withholdings) within ninety (90) days following the calendar year in which it was earned. The payment of any Bonus shall be subject to Executive's continued employment with the Company through the applicable payment date. Any dispute as to whether Executive has met the objectives shall be determined by the Compensation Committee in the exercise of its sole discretion, with Executive having the right to request that the Board review and confirm or reject such determination. The Company shall deduct from the Annual Bonus all amounts required to be deducted or withheld under applicable law or under any employee benefit plan in which Executive participates.

(c) Equity. Subject to and upon approval by the Board and the terms of the Company's 2018 Omnibus Stock Incentive Plan, as may be amended from time to time (the "***Plan***"), the Company shall grant Executive an option to purchase 120,000 shares of the Company's common stock (the "***Equity Award***"). The Equity Award shall be granted at a per share exercise price equal to the Fair Market Value (as defined in the Plan) of the Company's common stock on January 3, 2023, and shall be, to the maximum extent permissible, treated as an "incentive stock option" within the meaning of Section 422 of the of the Internal Revenue Code of 1986, as amended (the "***Code***"). The Equity Award shall vest one-third on the first (1st) anniversary of the Commencement Date (as defined in Section 2(a)), and the remainder in equal increments on each of the 24 one-month anniversaries thereafter, provided that Executive remains employed by Company on the vesting dates, except as otherwise set forth herein or in the Plan.

(d) Employee Benefits and Paid Time Off. While Executive is employed by the Company hereunder, Executive shall be entitled to participate in all employee benefit plans to the extent that Executive meets the eligibility requirements for each individual plan or program, including but not limited to participation in the Company's health, dental, and vision insurance plans for Executives, which shall be paid for by the Company. Such benefits are subject to change from time to time in accordance with the Company's plans. Executive shall be entitled to be paid for state and federal holidays recognized by the Company, and shall accrue paid time off ("***PTO***") in accordance with Company policy.

The Company reserve the right to amend, add, or discontinue benefits and PTO policies from time to time in its sole discretion.

(e) Reimbursement of Expenses. Executive shall be reimbursed for all ordinary and reasonable out-of-pocket business expenses incurred by Executive in furtherance of Company's business in accordance with Company's policies with respect thereto as in effect from time to time, upon presentation of documentation regarding such expenses. Executive must submit any request for reimbursement no later than ninety (90) days following the date that such business expense is incurred. If a business expense reimbursement is not exempt from Section 409A of the Internal Revenue Code ("***Section 409A***"), any reimbursement in one calendar year shall not affect the amount that may be reimbursed in any other calendar year and a reimbursement (or right thereto) may not be exchanged or liquidated for another benefit or payment. Any business expense reimbursements subject to Section 409A of the Code shall be made no later than the end of the calendar year following the calendar year in which Executive incurs such business expense.

4. Payments upon Termination.

(a) Definition of Accrued Obligations. For purposes of this Agreement, "***Accrued Obligations***" means the portion of Executive's Base Salary that has accrued prior to any termination of Executive's employment with Company and has not yet been paid, any accrued and unused vacation or sick leave to the extent required by applicable law, and the amount of any expenses properly incurred by Executive on behalf of Company prior to any such termination and not yet reimbursed consistent with the Company's policies. Executive's entitlement to any other compensation or benefit under any plan of Company shall be governed by and determined in accordance with the terms of such plans, except as otherwise specified in this Agreement.

(b) Termination by Company for Cause; by Company without Cause or by Executive without Good Reason within Executive's First Six (6) Months of Employment; or as a Result of Executive's Disability or Death. If Executive's employment hereunder is terminated by Company for Cause, by Company without Cause within Executive's first six (6) months of employment, by Executive without Good Reason, or as a result of Executive's Disability or death, then Company shall pay the Accrued Obligations to Executive promptly following the effective date of such termination and Executive shall not be eligible for payments or benefits described in Sections 4(c), 4(d) or 4(e) below.

(c) Termination by Company without Cause or by Executive for Good Reason Following Executive's First Six (6) Months of Employment. In the event that Executive's employment is terminated by action of Company other than for Cause, Disability or death at any time after Executive's first six (6) months of employment, then, in addition to the Accrued Obligations, Executive shall receive the following, subject to the terms and conditions of Section 4(e) below:

(1) Severance Payment. Payment in an amount equal to the Executive's then-existing Base Salary for a twelve (12) month period, less customary and

required taxes and employment-related deductions, paid in the form continued Base Salary; provided that such first installment payment shall be made within sixty (60) days following the effective date of termination from employment, and further provided that if the 60th day falls in the calendar year following the year during which the termination or separation from service occurred, then such first installment payment shall commence in such subsequent calendar year, with such first installment to include and satisfy all installments that would have otherwise been made up to such date assuming for such purpose that the installments had commenced on the first payroll date following the termination date.

(2) Benefits. Upon timely and proper completion of appropriate forms and subject to applicable terms and conditions under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("***COBRA"***), Company shall continue to provide Executive health insurance coverage at no cost to Executive, until the earlier to occur of twelve (12) months following Executive's termination date or the date Executive elects to participate in the group health plan of another employer. Subject to the Company's obligation under COBRA to provide timely notice, Executive shall bear responsibility for applying for COBRA continuation coverage.

The severance payments and benefits described in Section 4(d) below shall be *in lieu* of, and not in addition to, the severance payments and benefits described in this Section 4(c). Accordingly, in the event that Executive is eligible for the severance payments and benefits under Section 4(d) below, Executive shall not be eligible for the severance payments and benefits under this Section 4(c).

(d) Termination by Company Without Cause or by Executive for Good Reason Following a Change of Control. In the event that a Change of Control (as defined below) occurs, and within a period of thirty (30) days prior to or one (1) year following the Change of Control either Executive's employment is terminated by Company other than for Cause, Disability or death, or Executive terminates Executive's employment for Good Reason, then, in addition to the Accrued Obligations, Executive shall receive the following, subject to the terms and conditions in Section 4(e) below:

(1) Severance Payments. Payment in an amount equal to Executive's then-existing Base Salary for a twelve (12) month period, less customary and required taxes and employment-related deductions, paid in one lump sum amount on the first payroll date following the date on which the separation agreement under Section 4(e) below becomes effective and non-revocable; provided that such payment shall be made within sixty (60) days following the effective date of termination from employment, and further provided that if the 60th day falls in the calendar year following the year during which the termination or separation from service occurred, then the payment shall be made in such subsequent calendar year.

(2) Benefits Payments. Upon timely and proper completion of appropriate forms and subject to applicable terms and conditions under COBRA, Company shall continue to provide Executive medical insurance coverage at no

cost to Executive, until the earlier to occur of twelve (12) months following Executive's termination date or the date Executive elects to participate in the group health plan of another employer. Subject to the Company's obligation under COBRA to provide timely notice, Executive shall bear responsibility for applying for COBRA continuation coverage.

As used herein, a "***Change of Control***" shall mean the occurrence of any of the following events: (i) a merger or consolidation of Company, whether or not approved by the Board, other than a merger or consolidation which would result in the voting securities of Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or the parent of such entity) more than 50% of the total voting power represented by the voting securities of Company or such surviving entity or parent of such entity, as the case may be, outstanding immediately after such merger or consolidation; (ii) the acquisition of more than 50% of the voting power of the outstanding securities of the Company by one or more other entities, unless the Company's stockholders of record immediately prior to such acquisition will, immediately after such acquisition, hold at least 50% of the voting power of the Company, provided that a bona fide equity financing that the Board approves shall not constitute a Change of Control under this subsection (ii); or (iii) the sale or disposition by Company of all or substantially all of Company's assets in a transaction requiring Board approval.

The severance payments and benefits described in this Section 4(d) shall be *in lieu* of, and not in addition to, the severance payments and benefits described in Section 4(c) above. Accordingly, in the event that Executive is eligible for the severance payments and benefits under this Section 4(d), Executive shall not be eligible for the severance payments and benefits under Section 4(c) above.

(e) Execution of Separation Agreement. Notwithstanding any provisions in this Agreement to the contrary, Company shall not be obligated to pay Executive severance payments or benefits described in this Section 4 unless Executive has executed (without revocation) a timely separation agreement, which shall include a standard release of claims, the "***Separation Agreement***"); provided that the Separation Agreement shall be provided to Executive within ten (10) days following separation from service. Company shall not be obligated to pay Executive severance payments or benefits described in this Section 4 unless Executive has executed (without revocation) the separation agreement, and returned to Company no later than sixty (60) days following Executive's separation from service.

5. Confidentiality Agreement. In light of the competitive and proprietary aspects of the business of Company, and as a condition of employment hereunder, Executive agrees to execute and abide by the At-Will Employment, Confidentiality and Invention Assignment Agreement (the "***Confidentiality Agreement***"), entered into between Executive and Company on May 26, 2022, a copy of which is attached hereto as Exhibit A. Executive acknowledges that this Agreement constitutes a bona fide advancement within the Company and that the Executive has been given at least two (2) weeks' notice of the terms of the Confidentiality Agreement.

6. Return of Property and Records. Upon the termination of Executive's employment hereunder, or if Company otherwise requests at any time, Executive shall: (a) return to Company all tangible business information and copies thereof (regardless how such Confidential Information or copies are maintained), and (b) deliver to Company any property of Company which may be in Executive's possession, including, but not limited to, cell phones, smart phones, laptops, products, materials, memoranda, notes, records, reports or other documents or photocopies of the same.

7. Taxation.

(a) The intent of the parties is that payments and benefits under this Agreement comply with or otherwise be exempt from Section 409A and, accordingly, to the maximum extent permitted, this Agreement will be interpreted to be either exempt from or in compliance therewith, so that it shall not cause adverse tax consequences for Executive with respect to Section 409A, and any successor statute, regulation and guidance thereto. Executive acknowledges and agrees that Company does not guarantee the tax treatment or tax consequences associated with any payment or benefit arising under this Agreement, including but not limited to consequences related to Section 409A.

(b) In the event that the payments or benefits set forth in Section 4 of this Agreement constitute "non-qualified deferred compensation" subject to Section 409A, then the following conditions apply to such payments or benefits: (i) any termination of Executive's employment triggering payment of benefits under Section 4 of this Agreement must constitute a "separation from service" under Section 409A(a)(2)(A)(i) of the Code and Treas. Reg. §1.409A-1(h) before distribution of such benefits can commence; to the extent that the termination of Executive's employment does not constitute a separation of service under Section 409A(a)(2)(A)(i) of the Code and Treas. Reg. §1.409A-1(h) (as the result of further services that are reasonably anticipated to be provided by Executive to Company at the time Executive's employment terminates), any such payments under Section 4 of this Agreement that constitute deferred compensation under Section 409A shall be delayed until after the date of a subsequent event constituting a separation of service under Section 409A(a)(2)(A)(i) of the Code and Treas. Reg. §1.409A-1(h); for purposes of clarification, this Section 7(b) shall not cause any forfeiture of benefits on Executive's part, but shall only act as a delay until such time as a "separation from service" occurs; and (ii) notwithstanding any other provision with respect to the timing of payments under Section 4 of this Agreement if, at the time of Executive's termination, Executive is deemed to be a "specified employee" of Company (within the meaning of Section 409A(a)(2)(B)(i) of the Code), then limited only to the extent necessary to comply with the requirements of Section 409A, any payments to which Executive may become entitled under Section 4 of this Agreement which are subject to Section 409A (and not otherwise exempt from its application) shall be withheld until the first (1st) business day of the seventh (7th) month following the termination of Executive's employment, at which time Executive shall be paid an aggregate amount equal to the accumulated, but unpaid, payments otherwise due to Executive under the terms of Section 4 of this Agreement.

(c) It is intended that each installment of the payments and benefits provided under Section 4 of this Agreement shall be treated as a separate "payment" for purposes of Section 409A. Neither Company nor Executive shall have the right to accelerate or defer

the delivery of any such payments or benefits except to the extent specifically permitted or required by Section 409A. Notwithstanding any other provision of this Agreement to the contrary, this Agreement shall be interpreted and at all times administered in a manner that avoids the inclusion of compensation in income under Section 409A, or the payment of increased taxes, excise taxes or other penalties under Section 409A. The parties intend this Agreement to be in compliance with Section 409A.

(d) All reimbursements that would be considered nonqualified deferred compensation under Section 409A and provided under this Agreement shall be made or provided in accordance with the requirements of Section 409A including, where applicable, the requirement that: (i) any reimbursement is for expenses incurred during Executive's lifetime (or during a shorter period of time specified in this Agreement); (ii) the amount of expenses eligible for reimbursement during a calendar year may not affect the expenses eligible for reimbursement in any other calendar year; (iii) the reimbursement of an eligible expense shall be made no later than the last day of the calendar year following the year in which the expense is incurred; and (iv) the right to reimbursement or in kind benefits is not subject to liquidation or exchange for another benefit.

(e) If any payment or benefit Executive would receive under this Agreement, when combined with any other payment or benefit Executive receives pursuant to a Change of Control (for purposes of this Section 7(e), a "***Payment***") would: (i) constitute a "parachute payment" within the meaning of Section 280G the Code; and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "***Excise Tax***"), then such Payment shall be either: (A) the full amount of such Payment; or (B) such lesser amount as would result in no portion of the Payment being subject to the Excise Tax, whichever of the foregoing amounts, taking into account the applicable federal, state and local employments taxes, income taxes and the Excise Tax, results in Executive's receipt, on an after-tax basis, of the greater amount of the Payment notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. With respect to subsection (B), if there is more than one method of reducing the payment as would result in no portion of the Payment being subject to the Excise Tax, then Executive shall determine which method shall be followed, provided that if Executive fails to make such determination within thirty (30) days after Company has sent Executive written notice of the need for such reduction, Company may determine the amount of such reduction in its sole discretion.

8. Miscellaneous.

(a) Representations. Executive represents and warrants to the Company that (i) the execution, delivery and performance of this Agreement by Executive does not and will not conflict with, breach, violate or cause a default under any contract, agreement, instrument, order, judgment or decree to which Executive is a party or by which Executive is bound, and (ii) Executive is not a party to or bound by any employment agreement, noncompetition agreement or confidentiality agreement with any other person or entity (other than any such agreement with any affiliate or predecessor of the Company.

(b) Arbitration. Executive shall execute and deliver a Mutual Arbitration Agreement with the Company, a form of which is attached hereto as Exhibit B.

(c) Entire Agreement. This Agreement and Exhibits attached hereto, are intended to be the final, complete, and exclusive statement of the terms of Executive's employment by the Company. This Agreement supersedes all other prior and contemporaneous agreements, including Executive's May 3, 2022 Engagement Letter and Offer of Employment, and related amendments, and statements pertaining in any manner to the employment of Executive and it may not be contradicted by evidence of any prior or contemporaneous statements or agreements. Executive acknowledges that he does not rely upon any representations, oral or written, concerning the terms of his employment by the Company. To the extent that the practices, policies, or procedures of the Company, now or in the future, apply to Executive and are inconsistent with the terms of this Agreement, the provisions of this Agreement shall control.

(d) Amendments, Waivers. This Agreement may only be modified by an instrument in writing, signed by Executive and by a duly authorized representative of the Company other than Executive. No failure to exercise and no delay in exercising any right, remedy, or power under this Agreement shall operate as a waiver thereof, nor shall any single or partial exercise of any right, remedy, or power under this Agreement preclude any other or further exercise thereof, or the exercise of any other right, remedy, or power provided herein or by law or in equity.

(e) Assignment; Successors and Assigns. Executive agrees that the Executive will not assign, sell, transfer, delegate or otherwise dispose of, whether voluntarily or involuntarily, or by operation of law, any rights, or obligations under this Agreement, nor shall Executive's rights be subject to encumbrance or the claims of creditors. Any purported assignment, transfer, or delegation by Executive shall be null and void. Nothing in this Agreement shall prevent the consolidation of the Company with, or its merger into, any other corporation or entity, or the sale by the Company of all or substantially all of its properties or assets, or the assignment by the Company of this Agreement and the performance of its obligations hereunder to any affiliate or successor in interest, provided specifically that the Company may at any time assign all of its rights and obligations hereunder (including but not limited to the right to receive Executive's services as provided hereunder) to a third party purchaser. Subject to the foregoing, this Agreement shall be binding upon and shall inure to the benefit of the parties and their respective heirs, legal representatives, successors, and permitted assigns, and shall not benefit any person or entity other than those enumerated above.

(f) Notices. All notices and other communications required or permitted to be given hereunder shall be in writing and shall be deemed to have been duly given (i) upon receipt, if delivered personally or via courier, (ii) upon confirmation of receipt, if given by electronic mail, and (iii) on the third business day following mailing, if mailed first class, postage prepaid, registered, or certified mail from a United States address as follows or at such other address as each party hereafter designates:

to the Company at:

Attn: Chief Executive Officer
Eyenovia, Inc.
295 Madison Avenue, Suite 2400
New York, NY 10017

and to Executive at:

Bren Kern
[***]

(g) Severability; Enforcement. If any provision of this Agreement, or its application to any person, place, or circumstance, is held by an arbitrator to be invalid, unenforceable, or void, such provision shall be enforced (by blue penciling or otherwise) to the greatest extent permitted by law, and the remainder of this Agreement and such provision as applied to other persons, places, and circumstances shall remain in full force and effect.

(h) Governing Law. This agreement and the rights and obligations of the company and executive hereunder shall be determined under, governed by, and construed in accordance with the laws of the state of Oregon as applied to agreements among Oregon residents entered into and to be performed entirely within Oregon.

(i) Executive Acknowledgment. Executive acknowledges (i) that the Executive has consulted with independent counsel of the Executive's own choice concerning this Agreement and (ii) that the Executive has read and understands this Agreement, is fully aware of its legal effect, and has entered into it freely based on the Executive's own judgment.

(j) Counterparts. This Agreement may be executed by the parties hereto in separate counterparts, each of which when so executed and delivered shall be an original, but all such counterparts shall together constitute one and the same instrument. Delivery of an executed counterpart of the signature page to this Agreement by facsimile shall be as effective as delivery of a manually executed counterpart of this Agreement; provided, however, that any party so delivering an executed counterpart by facsimile shall thereafter promptly deliver a manually executed counterpart of this Agreement to the other parties, but failure to deliver such manually executed counterpart shall not affect the validity, enforceability and binding effect of this Agreement.

IN WITNESS WHEREOF, Executive and the Company, by its duly authorized agent, have each placed their signatures below.

Eyenovia, Inc.

/s/ Michael Rowe
By: Michael Rowe
Its: Chief Executive Officer

Executive

/s/ Bren Kern
Bren Kern

EXHIBIT A

CONFIDENTIALITY AGREEMENT

EXHIBIT B

MUTUAL ARBITRATION AGREEMENT

Please Read Carefully – By Signing This Document You Give Up Certain Legal Rights

1. Eyenovia, Inc., (the "Company") and the undersigned Employee ("Employee") have entered into this Mutual Agreement to Arbitrate Claims ("Agreement") in order to establish and gain the benefits of a timely, impartial, and cost-effective dispute resolution procedure. Employee understands that any reference in this Agreement to the Company will also be a reference to any and all benefit plans, the benefit plans' sponsors, fiduciaries, administrators, affiliates, and all successors and assigns of any of them.

2. Claims Covered by the Agreement: The Company and Employee mutually consent to the resolution by final and binding arbitration of all claims or controversies ("claims") arising out of Employee's employment (or termination) that the Company may have against Employee or that Employee may have against the Company or its officers, directors, employees, or agents. Final and binding arbitration shall provide the sole and exclusive remedy and forum for all such claims. The claims covered by this Agreement include, but are not limited to: (i) claims for discrimination or harassment on the basis of ancestry, age, color, marital status, medical condition, physical or mental disability, national origin, race, religion, pregnancy, sexual orientation, or any other characteristic protected by applicable law; (ii) claims for retaliation; (iii) claims for breach of any contract or covenant (express or implied); (iv) claims for wages or other compensation due; (v) claims for benefits (except where an employee benefit or pension plan specifies that its claim procedure shall culminate in a resolution procedure different from this one); (vi) claims for violation of any federal, state, or other governmental law, statute, regulation or ordinance now in existence, or hereinafter enacted, and amended from time to time; (vii) any tort claims (including, but not limited to, negligent or intentional injury, defamation, and termination of employment in violation of public policy), and (viii) individual claims for relief under the Private Attorneys General Act (PAGA) or any other similar federal, state, or local law.

3. **Waiver of Right to Court or Jury Trial and for Class Action Relief: The Company and Employee agree to give up their respective rights to have the above-mentioned claims decided in a court of law before a judge or jury or by administrative proceeding, and instead are accepting and agreeing to the use of final and binding arbitration. The sole exception to the foregoing is a hearing before the California Labor Commissioner on a claim for unpaid wages to the extent such agency has jurisdiction; however, any subsequent proceeding resulting from such a hearing that would otherwise be heard in a court of law, including any challenge or appeal of a decision rendered in such hearing, is subject to this Agreement and must be arbitrated. Employee also agrees and understands that Employee waives any right to bring claims as a class representative, or as a member of a collective action, and that any claims that Employee may bring must be brought solely in the Employee's individual capacity.**

4. Claims Not Covered by the Agreement: This Agreement does not cover: (i) claims by Employee for workers' compensation or unemployment insurance (an exclusive government-created remedy exists for these claims); (ii) claims for unpaid compensation or benefits within the

jurisdiction of the California Department of Labor Standards Enforcement; (iii) and (iv) claims which even in the absence of the Agreement could not have been litigated in court or before any administrative proceeding under applicable federal, state or local law. Nothing in this Agreement precludes either party from filing a charge or complaint with any state or federal administrative agency that prosecutes a claim on behalf of the government, for purposes of assisting or cooperating with such agency in its investigation or prosecution of charges or complaints. However, the parties waive their right to any personal remedy or relief as a result of such charges or complaints brought by such prosecuting agencies, to the extent that is permissible under law.

5. Notice of Claims and Statute of Limitations: All disputes between Employee and the Company (and its affiliates, shareholders, directors, officers, employees, agents, successors, attorneys, and assigns) relating to Employee's services with the Company or this Agreement, will be resolved by final and binding arbitration to the fullest extent permitted by law. Except as otherwise provided in this Agreement, the arbitration provisions are to apply to the resolution of disputes that otherwise would not be resolved in a court of law. All disputes must be brought within the applicable statute of limitations established by law and all claims must be sent via registered or certified mail, and shall identify and describe the nature of all claims asserted and the facts upon which such claims are based. Failure to comply with the requirements of this Section 4 may constitute a waiver of all rights that the party seeking arbitration may have against the other party.

6. Arbitration Procedures: The arbitration will be conducted in accordance with the then-existing JAMS Employment Arbitration Rules & Procedures, and as augmented in this Agreement. Arbitration will be initiated as provided by the JAMS Employment Rules. JAMS Employment Rules can be found at jamsadr.com/rules-employment-arbitration. Either Party may bring an action in court to compel arbitration under this Agreement and to enforce an arbitration award. Otherwise, neither Party will initiate or prosecute any lawsuit or administrative action in any way related to any applicable dispute or claim, except as set forth in this Agreement. All disputes or claims subject to arbitration will be decided by a single arbitrator. The arbitrator will be selected by mutual agreement of the Parties within thirty (30) days of the effective date of the notice initiating the arbitration. If the Parties cannot agree on an arbitrator, then the complaining Party will notify JAMS and request selection of an arbitrator in accordance with the JAMS Employment Rules or other applicable JAMS rules. The arbitrator will only have authority to award equitable relief, damages, costs, and fees as a court would have for the particular claims asserted, and any action of the arbitrator in contravention of this limitation may be the subject of court appeal by the aggrieved Party. All other aspects of the arbitrator's ruling will be final.

7. Arbitration Decision: The Arbitrator will issue a decision or award in writing, stating the essential findings of fact and conclusions of law. Except as may be permitted or required by law, all proceedings and all documents prepared in connection with any arbitration will be confidential and the arbitration subject matter will not be disclosed to any person other than the Parties to the proceedings, their counsel, witnesses and experts, the arbitrator, and, if involved, the court and court staff. The Parties will stipulate to all arbitration and court orders necessary to effectuate these confidentiality provisions. A court of competent jurisdiction will have the authority to enter a judgment upon the award made pursuant to the arbitration or applicable arbitration appeal.

8. Place of Arbitration: All arbitration proceedings will be conducted at a JAMS office located nearest to the location where the Employee was performing services for the Company.

9. Representation / Attorneys' Fees: Each party may be represented in the arbitration by an attorney or other representative selected by the party. Each party shall be responsible for its own attorneys' or representatives' fees, if any. However, if any party prevails on a statutory claim that affords the prevailing party attorneys' fees, the arbitrator may award reasonable attorneys' fees to the prevailing party in accordance with applicable law.

10. Discovery and Information Exchange: The arbitrator shall have discretion to order the scope of discovery and the pre-hearing exchange of information, consistent with the JAMS rules. The parties may engage in any method of discovery as outlined in the Federal Rules of Civil Procedure (exclusive of Rule 26(a)). Such discovery includes discovery sufficient to arbitrate adequately a claim, including access to essential and relevant documents and witnesses and the parties expressly empower the arbitrator to issue third-party document and deposition subpoenas. Discovery disputes are subject to the Federal Rules of Evidence and the Federal Rules of Civil Procedure.

11. Subpoenas: Each party shall have the right to subpoena witnesses and documents for the arbitration (including subpoenas to third parties for documents and depositions) and to issue document and testimonial subpoenas to third parties.

12. Injunctive Relief: Nothing in this Agreement is intended to prevent either party from obtaining injunctive or other emergent relief in a court to prevent irreparable harm pending the conclusion of any such arbitration.

13. Arbitrator Fees and Costs: If Employee initiates the arbitration, the Company will bear the cost of the arbitrator and the administrative fees associated with the arbitration proceeding. However, the Employee will be responsible for the portion of the initial filing fee equivalent to the cost of a filing fees Employee would be required to pay if the dispute were decided in a court of law.

14. Federal Arbitration Act: This Agreement is made under the provisions of the Federal Arbitration Act (9 U.S.C., Section 1-14) and will be construed and governed accordingly. Questions of arbitrability (that is whether an issue is subject to arbitration under this Agreement) shall be decided by the arbitrator.

15. Consideration: The Company's offer of employment to Employee, or continued employment of Employee, and the mutual promises of the Company and Employee to arbitrate claims covered by this Agreement rather than to litigate them, provide good and sufficient consideration for this Agreement.

16. Construction: Should any part of this Agreement be found to be unenforceable, such portion shall be severed from the Agreement, and the remaining portions shall continue to be enforceable.

17. Sole and Entire Agreement: This Agreement expresses the entire Agreement of the parties concerning the subject matter hereof and there are no other agreements, oral or written, concerning arbitration, except as provided herein. This Agreement is not, and shall not be construed to create any contract of employment, express or implied.

18. Requirements for Modification or Revocation: This Agreement to arbitrate shall survive the termination of Employee's employment. It can only be revoked or modified by a writing signed by the Board of Directors of the Company and Employee, which specifically states an intent to revoke or modify this Agreement.

19 Feedback. The Company desires this Agreement to be as clear and as straightforward as possible given the important subject matter. If you have any questions about this Agreement or have any suggestions on how the Company can modify it to improve your or your colleagues' understanding of its terms, please feel free to contact your supervisor or any manager or authorized Company officer at any time.

You are not obligated to enter into this Agreement. You also have the opportunity to request changes to this Agreement before you sign it. Please bring any such requested changes to the attention of the Company before you sign it.

By signing below, you represent:

You have carefully read this agreement, you understand its terms and you agree that all changes you have requested (if any) have been made to this Agreement.

You have been given the opportunity to consult with legal counsel about this Agreement.

You have been given sufficient time to read and understand this Agreement before signing it.

/s/ Bren Kern	12/18/2022
Bren Kern	Date

Eyenovia, Inc.

/s/ Michael Rowe	12/19/2022
By: Michael Rowe	Date
Its: Chief Executive Officer	

Exhibit 23.1

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statements of Eyenovia, Inc. on Form S-3 (File No. 333-229365, File No. 333-237790, File No. 333-261638 and File No. 333-268832) and Form S-8 (File No. 333-227049, File No. 333-233278, File No. 333-233280, File No. 333-246288, File No. 333-261035 and File No. 333-266823) of our report dated March 31, 2023, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, with respect to our audits of the financial statements of Eyenovia, Inc. as of December 31, 2022 and 2021 and for each of the two years in the period ended December 31, 2022, which report is included in this Annual Report on Form 10-K of Eyenovia, Inc. for the year ended December 31, 2022.

Our report on the financial statements refers to a change in the method of accounting for leases in 2022 due to the adoption of the guidance in ASC Topic 842, Leases effective January 1, 2022.

/s/ Marcum LLP

Marcum LLP
New York, NY
March 31, 2023

Exhibit 31.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE 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, 2022;

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: March 31, 2023

/s/ Michael Rowe
Name: Michael Rowe
Title Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF THE PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John Gandolfo, certify that:

1. I have reviewed this annual report on Form 10-K of Eyenovia, Inc. for the year ended December 31, 2022;

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: March 31, 2023

/s/ John Gandolfo

Name: John Gandolfo
Title Chief Financial Officer
(Principal Financial and Accounting 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, 2022, 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: March 31, 2023

/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, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John Gandolfo, Chief 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: March 31, 2023

/s/ John Gandolfo

Name: John Gandolfo
Title Chief Financial Officer
(Principal Financial and Accounting Officer)