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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, 2021**

**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: (917) 289-1117**
**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 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 ☐
Non-accelerated filer ☒
Emerging growth company ☒

Accelerated filer ☐
Smaller reporting 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. ☐

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, 2021 (based on the closing price of $4.96 on June 30, 2021, the last trading day of the registrant's most recently completed second fiscal quarter), was approximately $112,773,303. 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 31,698,424 as of March 30, 2022.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's proxy statement for its 2022 Annual Meeting of Stockholders currently scheduled to be held on June 16, 2022 are incorporated by reference into Part III hereof.

**Eyenovia, Inc.**
**Form 10-K**
**For Year Ended December 31, 2021**

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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 ("Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended ("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 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.
- We will need to raise additional capital in order to continue developing our product candidates and to potentially manufacture and commercialize them.
- Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies.
- We have incurred operating losses since our inception. We expect to continue to incur losses for the foreseeable future and might never achieve or maintain profitability.

RISKS RELATED TO 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 or our licensees may experience delays or difficulties in the enrollment and/or retention of patients in our clinical trials.
- 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.
- 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 marketing approval process for our product candidates is expensive, time-consuming and uncertain and may prevent us or our licensees from obtaining approvals for the commercialization.
- Our product candidates may cause undesirable side effects.
- The market opportunities for our product candidates may be smaller than we believe they are.
- The commercial success of our product candidates will depend in large part on the degree of market acceptance.
- Our licensing partners may fail to use commercially reasonable efforts to commercialize our products.
- We face competition in an environment of rapid technological change and our competitors may achieve regulatory approval before us or develop therapies that are more effective than ours.
- We might fail to establish and maintain effective manufacturing and distribution processes.
- 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 limit commercialization.

- 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.

RISKS RELATED TO REGULATORY APPROVAL AND LEGAL COMPLIANCE MATTERS

- We or our licensees might not be able to commercialize our product candidates.
- Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed in such jurisdictions.
- The term restrictions for our products in the U.S. and other jurisdictions in which we have licensed our products may limit how we manufacture and market our products.
- We may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products.
- Recently enacted and future legislation may affect our, or our licensees', ability to commercialize our products and the prices we obtain for any products that are approved in the U.S. or foreign jurisdictions.

RISKS RELATED TO OUR BUSINESS OPERATIONS AND MANAGING GROWTH

- We are highly dependent on the services of our senior management team.
- 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.

RISKS RELATED TO OUR DEPENDENCE ON THIRD PARTIES

- We rely on third parties to conduct, supervise and monitor clinical trials. 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 rely on third parties for the manufacture of components of our product candidates, who may have issues providing materials on time due to COVID-related supply chain disruptions.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY AND POTENTIAL LITIGATION

- Our success depends on our ability to protect our intellectual property, proprietary technology and trade secrets.
- 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.
- Changes to the patent law in the U.S. or other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.
- 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.

- 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.

RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK

- Our management and members of our Board of Directors have the ability to substantially influence all matters submitted to stockholders for approval.

- 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.

- The price of our common stock may be volatile and fluctuate substantially.

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

- Failure to develop and maintain adequate financial controls could cause us to have material weaknesses.

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

## 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 917-289-1117. 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 clinical stage ophthalmic company developing a pipeline of advanced therapeutics based on our proprietary microdose array print (MAP™) platform technology. We aim to achieve clinical microdosing of next-generation formulations of novel and existing ophthalmic pharmaceutical agents using our high-precision targeted ocular delivery system, branded the Optejet®. Optejet µ-therapeutics have the potential to replace conventional eye dropper delivery and improve safety, tolerability, patient compliance and topical delivery success for ophthalmic eye treatments. In the clinic, the Optejet has demonstrated that its targeted horizontal microdose delivery can achieve a significantly higher rate of successful ocular topical delivery compared to the established rate reported with traditional eye drops (~ 90% vs. ~ 50%). Our technology is designed to achieve single-digit µl-volume physiologic drug delivery with up to a 75% reduction in ocular drug and preservative topical dosing and has demonstrated significant improvement in the therapeutic index in drugs used for presbyopia, mydriasis and IOP lowering through six Phase II and Phase III trials. Conventional eye formulations lack high-precision micro-volume delivery and expose the ocular surface to approximately 300% more medication and preservatives than are physiologically indicated leading to clinically recognized ocular and non-ocular side effects. Using the Optejet, we are developing the next generation of smart ophthalmic therapeutics targeting new indications or new combinations where there are currently no or few drug therapies approved by the U.S. Food and Drug Administration, or the FDA. Our microdose therapeutics follow the FDA's regulatory and approval process for combination products. Our 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 FDA CDER for premarket review and approval under new drug applications, or NDAs.

Our pipeline is currently focused on the late-stage development of novel first-in-class therapeutic indications for an estimated over 25 million potential pediatric patients with progressive myopia in the United States and estimated over 100 million potential patients with age-related near vision impairment, or presbyopia – indications for which there is tremendous unmet need and, to our knowledge, there exists only one known FDA-approved therapy, developed by Allergan. We are also developing the first microdose fixed combination ophthalmic pharmaceutical for mydriasis to address the estimated over 100 million annual comprehensive eye exams with pupil dilation.

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 risk for high myopia. In February 2019, the FDA accepted our investigational new drug application, or IND, to initiate a Phase III registration trial of MicroPine (the CHAPERONE study) to reduce the progression of myopia in children. We enrolled the first patient in the CHAPERONE study in June 2019. Due to the COVID-19 pandemic, there have been delays in trial enrollment as a result of supply chain issues with our third party suppliers

On October 9, 2020, we entered into a License Agreement (the "Bausch License Agreement") with a subsidiary of Bausch Health Companies Inc. ("Bausch Health") pursuant to which Bausch Health 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 Health also will pay us royalties 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 Health assumed sponsorship of the IND as well as oversight and the costs related to the ongoing CHAPERONE study.

MicroLine (or Apersure™) is our 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 received FDA approval for and launch Vuity™, a pilocarpine solution for the treatment of presbyopia. We are currently enrolling our second Phase III study, VISION-2, using the same molecule but with the advantages of our Optejet delivery system. We anticipate top-line results from VISION-2 in mid-2022.

Mydcombi™ (or MicroStat) is our fixed combination formulation of tropicamide-phenylephrine for mydriasis, designed to be a novel approach for the estimated over 100 million office-based comprehensive and diabetic eye exams performed every year in the United States. We have 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 Complete Response Letter (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 are in the process of providing additional non-clinical device information and expect to file our NDA resubmission in the third quarter of 2022.

On August 10, 2020, we entered into a License Agreement (the "Arctic Vision License Agreement"), which was amended on September 14, 2021, with Arctic Vision (Hong Kong) Limited ("Arctic Vision"), 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, we received an upfront payment of $4.25 million before any payments to Senju Pharmaceutical Co., Ltd. ("Senju"). In addition, we may receive up to a total of $43.75 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 us or, for such products not supplied by us, pay us 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 the Exclusive License Agreement with Senju dated March 8, 2015, as amended by the License Amendment 2, executed on September 14, 2021. 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.

The following summarizes our product pipeline and anticipated milestones:

| Product Candidate | Indication | Next Expected Milestones |
|---|---|---|
| MicroLine | Improvement in Near Vision (Presbyopia) | Phase 3 VISION-2 Topline Results expected 2Q 2022 |
| MicroPine | Pediatric Myopia Progression (Near-Sightedness) | Phase 3 CHAPERONE Full Enrollment expected 4Q 2022 |
| Mydcombi | Pharmaceutical Mydriasis (Pupil Dilation) | Expected Refiling of NDA 3Q 2022 |

**Our Strategy**

Our goal is to become a leading developer and provider of advanced ophthalmic therapies based upon our 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, Eyenovia plans 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 10 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 who were 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 eyedrop 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 8 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.

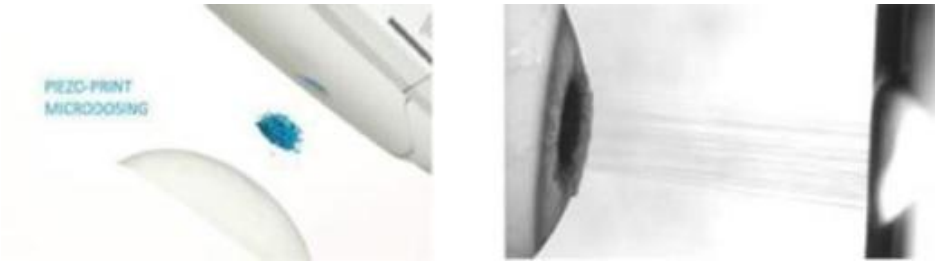
We believe that we are one of the only companies with clinical stage technology for targeted microdosing of ophthalmic investigational therapies having fully completed the Phase III clinical studies needed and made an NDA submission. The Optejet is based on MAP, which is also used for pixel-sharp high-precision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

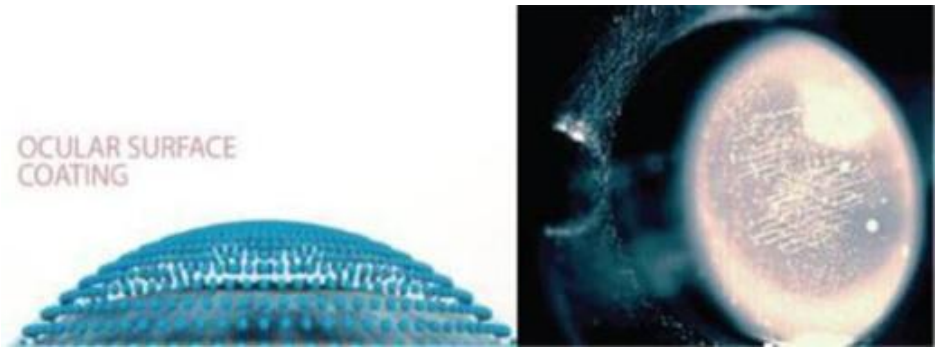
Microdose administration of topical ophthalmic drugs with the Optejet has been tested in preclinical models and clinical trials and shown to provide many advantages over administrations of eye drops. Key advantages of the Optejet include:

***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.



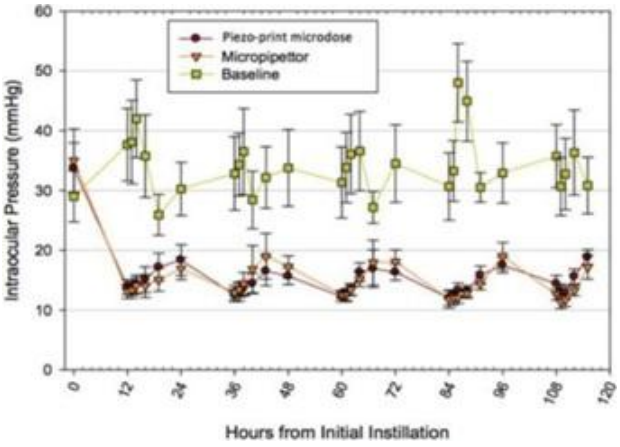
***Smart electronics:*** A key feature of the Optejet is the embedded electronic, Bluetooth enabled "e-health" system, which we believe is the first intelligent electronic delivery system for ophthalmic therapies. Our electronic functions are designed to enable patients and physicians to track when doses 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**

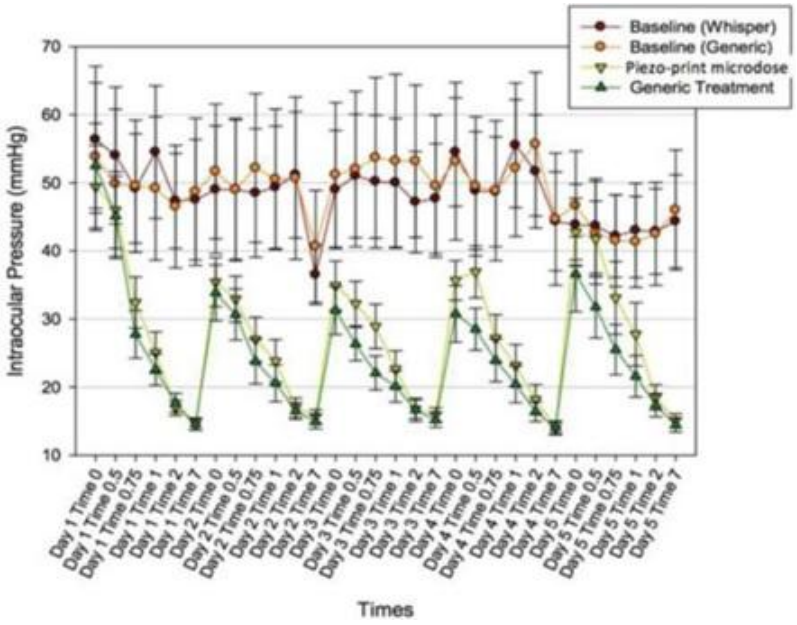
We have an established platform for microdose administration of ophthalmic solutions. Our preclinical and clinical studies suggest that a microdose of approximately 8 µL of medication results in clinical efficacy comparable to that of traditional eye drops, with the advantages of fewer ocular side effects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



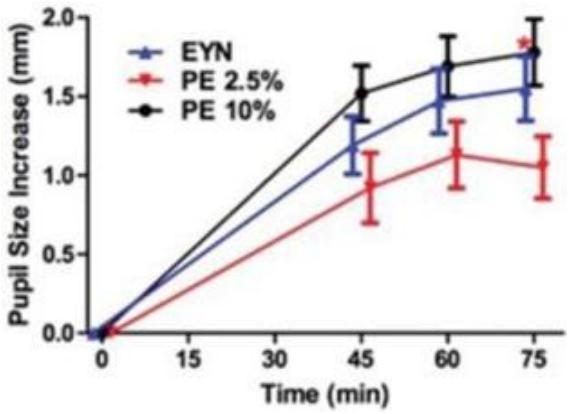
**IOP Lowering Effect of Micro-Therapeutic Dose of Latanoprost in Canine Model**



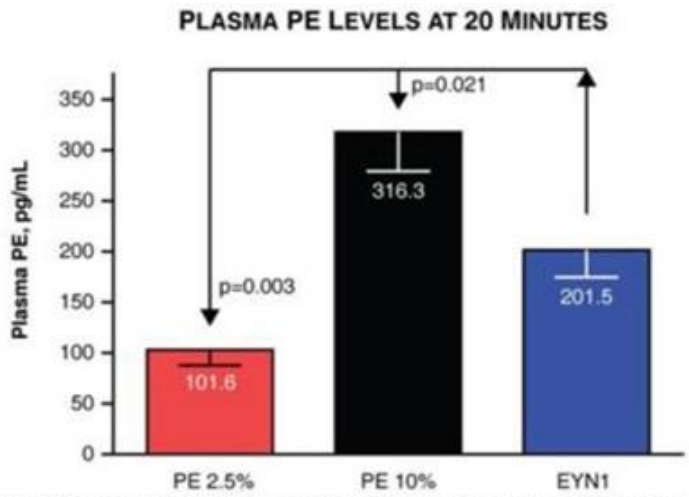

The Phase II EYN-1601 clinical trial compared the mydriatic effect of phenylephrine 10% microdosed (~7 µL in volume) with the Optejet (EYN) to phenylephrine 10% (PE 10%) and phenylephrine 2.5% (PE 2.5%) eye drops (each ~32 µL in volume) in 24 eyes. At 75-minute peak dilation, our microdose provided similar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



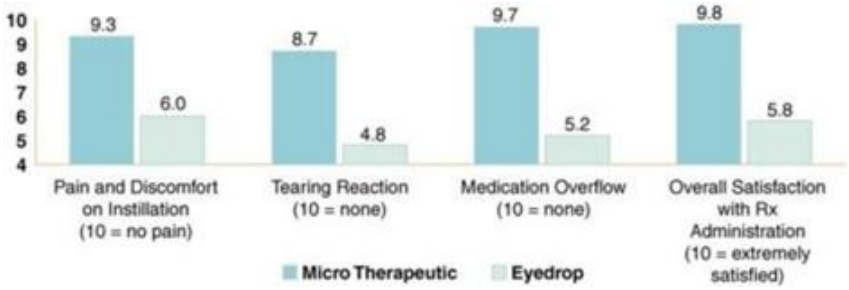

**Plasma free PE concentration in venous blood drawn 20 minutes after ocular topical drug administration. Circulating PE was highest in PE 10% subjects (316.3±36.8 pg/mL), and was significantly 36.3% lower in EYN subjects (201.5±27.1 pg/mL; p=.021). Plasma PE was significantly lower in PE 2.5% subjects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

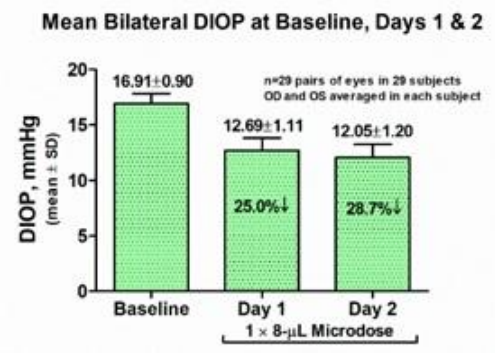
**OCULAR ADVERSE EVENTS BY TREATMENT**

| 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.

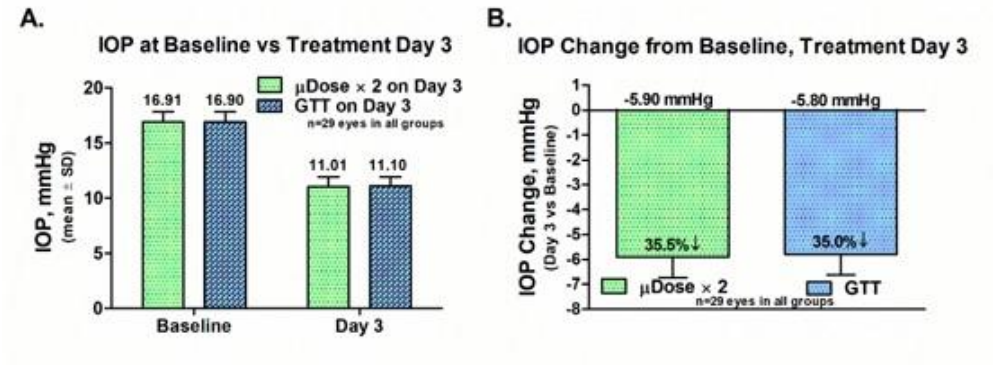


In 2018, Eyenovia completed a third early phase trial (EYN-POC-PG-21) to extend the findings of the two previous trials evaluating Optejet administration of mydriatic agents. This study was a single-center, open-label, prospective, crossover design evaluating the usability, patient tolerability, and 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 (DIOP) was calculated from the four readings. As shown below, mean DIOP after medication administration on Days 1 and 2 was lowered by 25.0% and 28.7%, respectively.




*Mean bilateral DIOP and percent change in DIOP 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 DIOP 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%.




**DIOP 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 DIOP 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 (also known as Apersure™)**

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 is currently enrolling with expected top-line results in mid-2022. The VISION-2 study will evaluate the safety, tolerability, and efficacy of Optejet-administered microdosing of pilocarpine 2% as an ophthalmic spray versus placebo.

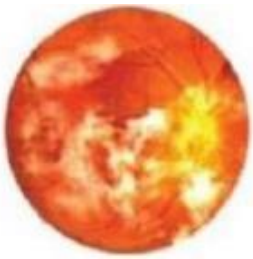
**MicroPine**

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

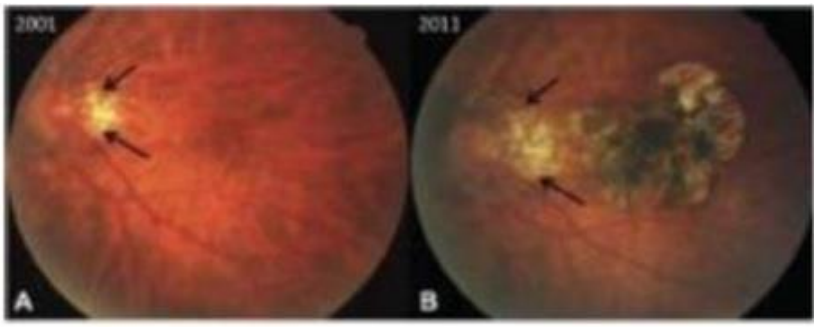
***Background of Progressive Myopia and Market Opportunity***

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.

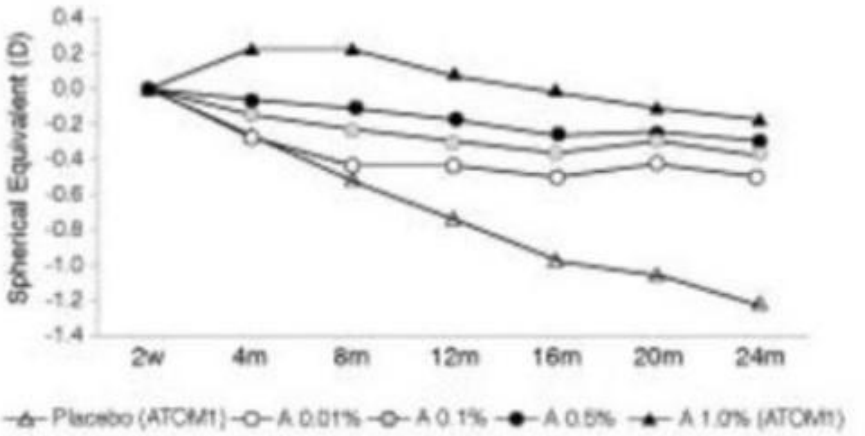



**Figure 2.** Mean change in spherical equivalent for groups from baseline, 2 weeks, and 4 to 24 months with atropine 0.01%, 0.1%, and 0.5% from the ATOM2 study, and placebo and atropine 1.0% from the ATOM1 study. A = atropine; ATOM = Atropine for the Treatment of Myopia; D = diopter; m = month; w =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

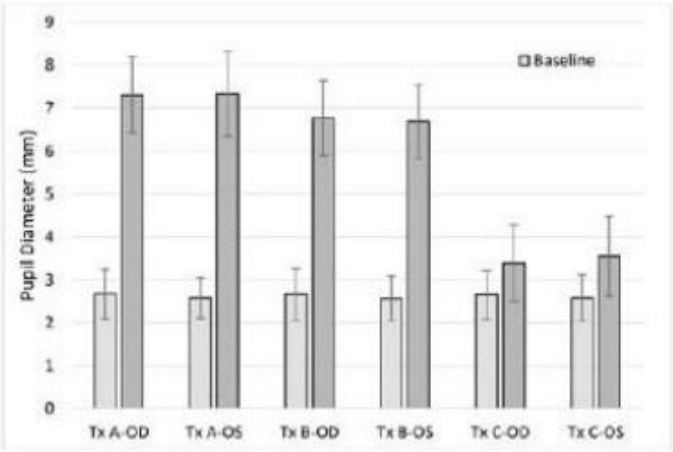
Volunteer participants were evaluated for study eligibility during a screening visit and enrolled after providing study consent. Subjects meeting all inclusion/exclusion criteria were scheduled for three treatment visits, which occurred at least two days, but no more than seven days apart. At each treatment 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.

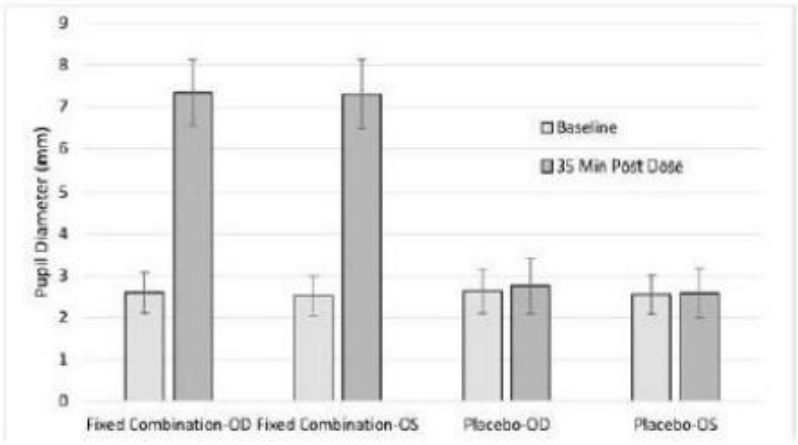
Volunteer participants were evaluated for study eligibility during a screening visit and enrolled after providing study consent. Subjects meeting all inclusion/exclusion criteria were scheduled for three treatment visits, which occurred at least two days, but no more

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<br>4.7 mm left eyes | 4.7 mm right eyes<br>4.8 mm left eyes |
| Proportion of eyes with pupil diameter ≥ 6.0 mm at 35 minutes | 95.2% of right eyes<br>93.5% of left eyes | 92.8% of right eyes<br>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 are in the process of providing additional non-clinical device information and expect to file our NDA resubmission for Mydcombi in the third quarter of 2022.

We conducted a Phase IV study (SPEED) during May - June 2021 to further understand the performance of an ophthalmologic fixed combination tropicamide-phenylephrine product (T-P OFTENO SOLUCIÓN) delivered by the Optejet dispenser. The objective of the study was to evaluate the onset speed of dilation and compare effectiveness of one microdose spray (approximately 8 µl) with the Optejet® vs. two sprays. Sixty patients (120 eyes) were randomized with a mean age of 40.3 ± 14.2 years, 62% were female, and 98% were Hispanic or Latino. At 15 minutes post-administration, a clinically meaningful pupil diameter (≥ 6.0 mm) was achieved in more than two thirds of patients with both one and two sprays. No statistical difference in pupil dilation was found between one and two sprays administered at each observed timepoint. No serious adverse events were reported in the study. The SPEED study validates that there is no clinical difference in using one or two sprays, clinically relevant pupil diameters can be quickly achieved post-spray, and it offers users a well-tolerated and efficient way to administer topical ophthalmic medications. The results of the SPEED study will be presented at the 2022 annual meeting of the American Society of Cataract and Refractive Surgery.

**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 is expected to come on-line with the production of clinical materials in mid-2022.

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

The drug products used in the Eyenovia devices are produced by domestic third-party manufacturers. We expect to continue to rely upon CMOs for the manufacture of our clinical trial materials and to fulfill initial commercial product demand. Critical vendor relationships are governed by specific agreements or purchase order terms. If any of our existing third party suppliers should become unavailable to us for any reason, we believe that there are a number of potential replacements, although we might experience a delay in our ability to obtain alternatively sourced quantities of materials or services due to their unique and specialized nature. We have also experienced supply chain delays due to the COVID-19 pandemic, which in some cases have resulted in the delay in the manufacturing of our products. We believe that these delays may be resolved in 2022.

**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 recently 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 has filed three petitions for *inter partes* review (“IPR”) directed at 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.

***Patents***

As of December 31, 2021, we owned thirteen U.S. issued and allowed utility patents or design patents, and multiple pending U.S. patent applications, as well as 84 issued foreign patents, and multiple 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 preclinical laboratory tests, 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 practices, or GCP, 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 Practices, 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 GCPs 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 Studies***

Preclinical studies include laboratory evaluation of the purity and stability of the manufactured drug substance or active pharmaceutical ingredient and the formulated drug or drug product, as well as *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 results of the preclinical 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 preclinical 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.

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.

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.

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 recently begun enforcing those requirements 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.

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 full, 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 an application user fee, which for federal fiscal year 2022 exceeds $3.1 million for an application requiring clinical data. The sponsor of an approved NDA is also subject to an annual prescription drug program fee, which for fiscal year 2022 exceeds $360,000. 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 ten 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. 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 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 was not required (i.e., a Class II device). 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. 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, will require 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 or life-supporting. 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, preclinical, 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 premarket approval applications or premarket approval 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 down-classification of its medical device into 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. Prior to the enactment of FDASIA, a medical device could only be eligible for De Novo classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent. FDASIA streamlined the De Novo classification pathway by permitting manufacturers to request De Novo classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. 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.

In October 2021, the FDA issued a final rule that would formally codify requirements for the medical device De Novo process and the procedures and criteria for product developers to file a De Novo classification request (86 Fed. Reg. 54,826). Over the twenty years preceding the final rule, the De Novo process has been implemented by the FDA pursuant to statutory authorities and somewhat organically through informal guidance and iterative changes by Congress. Although the final rule does not affect marketed

products such as our marketed products, the FDA's goals in promulgating the final rule are to create a predictable, consistent and transparent De Novo classification process for innovative medical device developers.

***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;
- 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.

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 studies supporting the drug registration, the applicant submits the drug marketing authorization application according to the 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 Drug Evaluation Center (CDE) review the accepted drug marketing authorization applications. After a comprehensive review they issue a registration certificate of approval for drugs. 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 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) etc. 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 and teaching hospitals or to entities or individuals at the request of, or designated on behalf of, the physicians (defined broadly to include certain advanced practice health care professionals) 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.

In November 2020, HHS finalized significant changes to the regulations implementing the Anti-Kickback Statute, as well as the Physician Self-Referral Law (Stark Law) and the civil monetary penalty rules regarding beneficiary inducements, with the goal of offering the healthcare industry more flexibility and reducing the regulatory burden associated with those fraud and abuse laws, particularly with respect to value-based arrangements among industry participants.

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 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. For example, in December 2016, the 21st Century Cures Act (the "Cures Act") was signed into law. The Cures Act, among other things, was intended to modernize the regulation of drugs and devices and to spur innovation, but its ultimate implementation is uncertain. Legislative proposals continue to be discussed in the U.S. Congress as potentially leading to a future "Cures 2.0" bill that is expected to have bipartisan support. In addition, in August 2017, the FDA Reauthorization Act was signed into law, which reauthorized the FDA's user fee programs and included additional drug product provisions. The next legislative reauthorization must be completed in 2022, which has the potential to make further changes to FDA authorities or policies pertaining to biopharmaceutical products. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we 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.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the Affordable Care Act. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the Affordable Care Act brought by several states without specifically ruling on the constitutionality of the Affordable Care Act. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the Affordable Care Act will impact the Affordable Care Act or our business.

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. Among other things, the executive order directs the FDA to work towards implementing a system for importing drugs from Canada (following on a Trump administration notice-and-comment rulemaking on Canadian drug importation that was finalized in October 2020). The Biden order also called on HHS to release a comprehensive plan to combat high prescription drug prices, and it includes several directives regarding the Federal Trade Commission's oversight of potentially anticompetitive practices within the pharmaceutical industry. 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. 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 will remain in effect through 2030 unless additional Congressional action is taken. However, due to COVID-19 pandemic relief legislation, the 2% Medicare sequester reductions were suspended from May 1, 2020 through June 30, 2021 (a 1% sequester will apply from April 1, 2022 through June 30, 2022), and the sequester was extended in order to offset the added expense of the 2020 suspension. Further legislative and regulatory changes under the ACA remain possible, although the new administration under President Biden has signaled that it plans to build on the ACA and expand the number of people who are eligible for health insurance subsidies under it. President Biden indicated that he intends to use executive orders to undo changes to the ACA made by the former administration and would advocate for legislation to build on the ACA. It is unknown what form any such changes or any law would take, and how or whether it may affect the pharmaceutical industry as a whole or our business in the future. We expect

that changes or additions to the ACA, the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug prices, 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.

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.

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.

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. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic.

**Human Capital Resources**

As of March 15, 2022, we had 45 total employees, including 43 full-time and 2 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 a number of additional employees during 2022. 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.

**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, 2021 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, 2021, indicating that, without additional sources of funding, our cash at December 31, 2021 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.

***We will need to raise additional capital in order to continue developing our product candidates and to potentially 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, we may attempt 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.

***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 $90.2 million since inception, have not generated any product sales revenue and have not achieved profitable operations. Our net losses were approximately $12.8 million and $19.8 million for the years ended December 31, 2021 and 2020, 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 drug. 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; and
- 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 and MicroLine in Greater China and South Korea, and Senju, for the development and commercialization of MicroPine and MicroLine in Asia (other than Greater China and South Korea). We also submitted an NDA for Mydcombi for pharmacologic mydriasis and initiated our Phase III Chaperone 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, 2021, we had federal net operating loss carry-forwards of approximately $60.0 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 our Mydcombi for mydriasis, MicroPine for pediatric progressive myopia, and MicroLine for presbyopia product candidates. Our prospects are substantially dependent on our ability 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 Phase III trial 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 participant recruitment and enrollment;
- higher than anticipated participant drop-out rates;
- failure of clinical trial participants 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;
- participants 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 quality control/quality assurance procedures necessary for study database lock and analysis of unblinded data.

The COVID-19 pandemic remains an uncertain additional risk to our timelines for commencement and completion of our clinical trials. Our prospective or contracted clinical trial sites may temporarily suspend activities at their sites to help secure the safety of their employees or to adhere to government recommendations or orders related to social distancing and limiting public gatherings, or they may experience resource constraints stemming from the pandemic and become unable to allocate adequate resources to reach agreements necessary to commence our clinical trials at their facilities or, even if agreements are in place, to conduct our clinical trials. For clinical trials that we are able to initiate, we may experience lower than anticipated subject enrollment and completion rates, including because individuals may avoid medical settings due to concerns related to the pandemic or they may become subject to governmental orders or recommendations that impose curfews or that ask individuals to leave their homes only if essential. In addition, increased rates of worker illness and implementation of work-from-home and restricted travel policies due to the COVID-19 pandemic may delay any regulatory authority and/or IRB approvals necessary for our clinical trials and/or prevent our CROs and other third-party contractors who are necessary for the conduct of our clinical trials from meeting their contractual obligations to us in a timely manner, any of which could delay commencement and completion of our clinical trials.

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 patients. Patient 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 patient enrollment taking longer than anticipated or patient 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 the COVID-19 pandemic, including difficulties in initiating clinical sites, enrolling and retaining participants, diversion of healthcare resources away from clinical trials, travel or quarantine policies that may be implemented, and other factors;
- potential disruptions caused by geopolitical events such as the Russian invasion of Ukraine;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and

- the proximity and availability of clinical trial sites for prospective patients.

Inability to enroll a sufficient number of patients 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.

***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 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.

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.

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;
- 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; 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 are in the process of providing additional non-clinical device information and expect to file our NDA resubmission for Mydcombi in the third quarter of 2022. However, even if we address 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 the Mydcombi for commercialization, which would materially adversely impact our business.

***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;
- 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 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; and
- injunctions or the imposition of civil or criminal penalties;

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.

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 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 (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 related to ownership and investment interests and payments and/or other transfers of value made to or held by physicians (defined broadly to include doctors, dentists, optometrists, podiatrists, chiropractors, and other advanced practice health care professionals) and teaching hospitals. 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) beginning on 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, although the new federal administration under President Biden has signaled that it plans to build on the ACA and expand the number of people who are eligible for health insurance subsidies under it. 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 allowing the federal government to directly negotiate drug prices, 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 health care industry in the US.

In the United States and in some other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the health care system that could prevent or delay marketing approval of our drug candidates, restrict or regulate post-approval activities, or affect our ability to profitably sell any drug candidates for which we obtain marketing approval, if any. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, was intended to modernize the regulation of drugs and devices and to spur innovation, but its ultimate implementation is uncertain. Legislative proposals continue to be discussed in the U.S. Congress as potentially leading to a future "Cures 2.0" bill that is expected to have bipartisan support. In addition, in August 2017, the FDA Reauthorization Act was signed into law, which reauthorized the FDA's user fee programs and included additional drug and biological product provisions. The next legislative reauthorization must be completed in 2022, which has the potential to make further changes to FDA authorities or policies pertaining to biopharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals, if any, of our drug candidates, may be or whether such changes will have any other impacts on our business. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing conditions and other requirements.

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, and the recent transition to a new Democrat-led presidential administration created further uncertainty in the health care and biopharmaceutical

industries. 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. Among other things, the executive order directs the FDA to work towards implementing a system for importing drugs from Canada (following on a Trump administration notice-and-comment rulemaking on Canadian drug importation that was finalized in October 2020). The Biden order also called on HHS to release a comprehensive plan to combat high prescription drug prices, and it includes several directives regarding the Federal Trade Commission's oversight of potentially anticompetitive practices within the pharmaceutical industry. 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.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, California requires pharmaceutical manufacturers to notify certain purchasers, including health insurers and government health plans at least 60 days before any scheduled increase in the wholesale acquisition cost ("WAC"), of their product if the increase exceeds 16%, and further requires pharmaceutical manufacturers to explain whether a change or improvement in the product necessitates such an increase. Similarly, Vermont requires pharmaceutical manufacturers to disclose price information on certain prescription drugs, and to provide notification to the state if introducing a new drug with a WAC in excess of the Medicare Part D specialty drug threshold. In December 2020, the U.S. Supreme Court also held unanimously that federal law does not preempt the states' ability to regulate pharmaceutical benefit managers, 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. 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.***

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.

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.

***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.***

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.

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.

## 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 Chief Medical Officer, Dr. Ianchulev, 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 and Chief Medical Officer, Dr. Ianchulev. 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 pharmaceutical 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. Our failure to integrate these individuals and create effective working relationships among.

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

As of March 15, 2022, we had only 43 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. These risks are heightened as a result of the efforts of government agencies and the CROs themselves to limit the spread of COVID-19, including quarantines and shelter-in-place orders. 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 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, or any impacts on our suppliers due to the COVID-19 pandemic, 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 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, recent 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 shares. 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 30,2022, we had 31,698,424 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 6,740,260 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 February 2022 as a result of the Russian invasion of Ukraine. 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, 2022, the per share trading price of our common stock has been as high as $10.74 and as low as $1.77. 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 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.

***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 1,000 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 1,300 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.

**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 30, 2022, we had approximately 34 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, 2021 and 2020, 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 clinical stage ophthalmic company developing a pipeline of advanced therapeutics based on our proprietary microdose array print (MAP™) platform technology. We aim to achieve clinical microdosing of next-generation formulations of novel and existing ophthalmic pharmaceutical agents using our high-precision targeted ocular delivery system, branded the Optejet®. Optejet µ-therapeutics have the potential to replace conventional eye dropper delivery and improve safety, tolerability, patient compliance and topical delivery success for ophthalmic eye treatments. In the clinic, the Optejet has demonstrated that its targeted horizontal microdose delivery can achieve a significantly higher rate of successful ocular topical delivery compared to the established rate reported with traditional eye drops (~ 90% vs. ~ 50%). Our technology is designed to achieve single-digit µl-volume physiologic drug delivery with up to a 75% reduction in ocular drug and preservative topical dosing and has demonstrated significant improvement in the therapeutic index in drugs used for presbyopia, mydriasis and IOP lowering through six Phase II and Phase III trials. Conventional eye formulations lack high-precision micro-volume delivery and expose the ocular surface to approximately 300% more medication and preservatives than are physiologically indicated leading to clinically recognized ocular and non-ocular side effects. Using the Optejet, we are developing the next generation of smart ophthalmic therapeutics targeting new indications or new combinations where there are currently none or few drug therapies approved by the U.S. Food and Drug Administration, (the "FDA"). Our microdose therapeutics follow the FDA's regulatory and approval process for combination products. Our products are classified by the FDA as drug-device combination drug/-device 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 FDA CDER for premarket review and approval under new drug applications, or NDAs.

Our pipeline is currently focused on the late-stage development of novel, potential first-in-class therapeutic indications for an estimated 25 million potential pediatric patients with progressive myopia in the United States and an estimated over 100 million potential patients with age-related near vision impairment, or presbyopia – indications where there is tremendous unmet need and, to our knowledge, there exists only one known FDA-approved therapy, developed by Allergan. We are also developing the first microdose fixed combination ophthalmic pharmaceutical for mydriasis to address the estimated over 100 million annual comprehensive eye exams with pupil dilation.

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 risk for high myopia. In February 2019, the FDA accepted our investigational new drug application, or IND, to initiate a Phase III registration trial of MicroPine (the CHAPERONE study) to reduce the progression of myopia in children. We enrolled the first patient in the CHAPERONE study in June 2019. Due to the COVID-19 pandemic, there have been delays in trial enrollment as a result of supply chain issues with our third party suppliers, which in turn diminished our inventory supply.

On October 9, 2020, we entered into the Bausch License Agreement, pursuant to which Bausch Health 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 Health also will pay us royalties 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 Health assumed sponsorship of the IND as well as oversight and the costs related to the ongoing CHAPERONE study.

MicroLine (or Apersure) 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 received FDA approval for and launched Vuity™, a pilocarpine solution for the treatment of presbyopia. We are currently enrolling our second Phase III study, VISION-2, using the same molecule, but with the advantages of our Optejet delivery system. We anticipate top-line results from VISION-2 in mid-2022.

Mydcombi™ (or MicroStat) is our fixed combination formulation of tropicamide-phenylephrine for mydriasis, designed to be a novel approach for the estimated over 100 million office-based comprehensive and diabetic eye exams performed every year in the United States. We have 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 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 are in the process of providing additional non-clinical device information and expect to file our NDA resubmission in the third quarter of 2022.

On August 10, 2020, we entered into the Arctic Vision License Agreement, which was amended on September 14, 2021, with Arctic Vision, 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, we received an upfront payment of $4.25 million before any payments to Senju. In addition, we may receive up to a total of $43.75 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 us or, for such products not supplied by us, pay us 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 the Exclusive License Agreement with Senju dated March 8, 2015, as amended by the License Amendment 2, executed on September 14, 2021. 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.

Historically, we have financed our operations principally through equity offerings. We have also generated cash through licensing arrangements and our credit facility with Silicon Valley Bank ("SVB"). 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 $12.8 million and $19.8 million for the years ended December 31, 2021 and 2020. As of December 31, 2021, we had working capital and an accumulated deficit of approximately $10.8 million and $90.2 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, 2021 and 2020.

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, 2021 Compared with Year Ended December 31, 2020***

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. On September 14, 2021, we executed Amendment 1 to the Arctic Vision License Agreement with Arctic Vision, 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. In December 2020, we satisfied the performance obligation which resulted in us recognizing $2.0 million of milestone revenues. We did not recognize revenue for the $250,000 upfront payment because it was passed through to Senju pursuant to our agreement with them. 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 on the accompanying statements of operations. See Note 10 – Related Party Transactions in the accompanying financial statements for the years ended December 31, 2021 and 2020.

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.

Research and Development Expenses

Research and development expenses for the year ended December 31, 2021 totaled $14.5 million, an increase of $1.1 million, or 9%, as compared to $13.4 million recorded for the year ended December 31, 2020. Research and development expenses consisted of the following:

| | For the Year Ended December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Direct clinical and non-clinical expenses | $ 4,928,674 | $ 6,206,239 |
| Personnel-related expenses | 5,393,241 | 3,747,847 |
| Supplies and materials | 1,271,234 | 1,448,787 |
| Non-cash stock-based compensation expenses | 1,612,942 | 1,350,894 |
| Facilities expenses | 928,832 | 138,348 |
| Other expenses | 374,602 | 471,136 |
| Total research and development expenses | $ 14,509,525 | $ 13,363,251 |

The decrease in direct clinical and non-clinical expenses was primarily due to the Vision I Study having concluded in early 2021 and significantly higher cost reimbursements from Bausch Health and Arctic Vision. The cost reimbursements are booked as contra expense. The increase in personnel-related expenses is primarily due to new hires and 2021 salary increases in the R&D group in preparation for commercialization. The decrease in supplies and materials is primarily due to us producing the bulk of our current 2021 needs for clinical cartridge supply in 2020. The increase in stock-based compensation expense is primarily due to stock option grants for new hires and executives in 2021. The increase in facilities and other expenses was primarily due to rent and utilities related to the new Redwood City facility in preparation for commercialization. The increase in other expense primarily reflects the depreciation of additional equipment purchased for clinical trials.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2021 totaled $10.8 million, an increase of $3.2 million, or 42%, as compared to $7.6 million recorded for the year ended December 31, 2020. The increase was primarily attributable to increases of approximately $0.9 million in payroll related expenses due to new hires, bonuses, and salary raises, increases in stock-based compensation of approximately $0.1 million due to option grants to new hires and officers, an increase of approximately $1.5 million in sales and marketing, primarily related to the Mydcombi promotional campaign, an increase of approximately $0.3 million in insurance expenses, an increase of approximately $0.2 million in travel and conference expenses primarily due to a decreased impact of COVID-19 austerity measures, an increase of approximately $0.1 million due to a one-time fee paid towards a commercial product distribution wholesale service in 2021 and an increase of approximately $0.1 million in investor relations.

Other Income (Expense)

Other income (expense) for the year ended December 31, 2021 totaled approximately $125,000 of income, an increase of approximately $106,000, or 558%, as compared to $19,000 of income for the year ended December 31, 2020. The increase was primarily due to approximately $463,000 of other income recorded as a gain on extinguishment of the PPP (7a) loan, offset by an increase of approximately $371,000 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, | |
|---|---|---|
| | 2021 | 2020 |
| Cash and Cash Equivalents | $ 19,461,850 | $ 28,371,828 |
| Restricted Cash | 7,875,000 | — |
| Total | $ 27,336,850 | $ 28,371,828 |
| Working Capital | $ 10,829,363 | $ 15,192,968 |
| Notes Payable (Gross) | $ 7,500,000 | $ 463,353 |

*Cash Flow*

Since inception, we have experienced negative cash flows from operations and our operations have primarily been funded through proceeds received in equity and debt financings. At December 31, 2021, our accumulated deficit since inception was approximately $90.2 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, 2021 and 2020, our sources and uses of cash were as follows:

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 non-cash expenses. Net cash used in operating activities for the year ended December 31, 2020 was approximately $6.4 million, which includes cash used to fund a net loss of $19.8 million, reduced by $2.6 million of non-cash expenses, offset by $10.8 million of net cash provided by changes in the levels of operating assets and liabilities.

Net cash used in investing activities was approximately $1.6 million and $0.3 million for the years ended December 31, 2021 and 2020, respectively, which was attributable to purchases of property and equipment.

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 LLC (formerly known as SVB Leerink LLC), $2.1 million of proceeds from exercises of stock warrants, $7.5 million of proceeds from the credit facility with SVB, $0.2 million of proceeds from the exercise of stock options, offset by $0.7 million from the repayment of notes payable and $0.1 million from the payment of loan issuance costs. Net cash provided by financing activities for the year ended December 31, 2020 totaled approximately $20.9 million, which was primarily attributable to $12.4 million of net proceeds from the sale of common stock in our August 2020 public offering, $5.6 million of net proceeds from the sale of common stock and warrants in our March 2020 private placement, $2.9 million of proceeds from the exercise of warrants issued in our March 2020 private placement and stock options held by certain employees, and $0.5 million from the proceeds of the PPP Loan, offset by $0.5 million from the repayment of notes payable.

In addition, on March 3, 2022, we raised approximately $15 million through the issuance and sale of 3,000,000 shares of common stock, pre-funded warrants to purchase an aggregate of 1,870,130 shares of common stock and warrants to purchase an aggregate of 4,870,130 shares of common stock at an exercise price of $3.54 per share.

Subsequent to December 31, 2021, we received approximately $0.9 million in gross and net proceeds from the sale of 252,449 shares of our common stock pursuant to an at-the-market offering.

**Contractual Obligations and Commitments**

During the next twelve months we have commitments to pay (a) $4.0 million to settle our December 31, 2021 accounts payable and accrued expenses, (b) $0.5 million relating to our non-cancelable operating lease commitments; (c) $1.3 million of potential executive severance pay; and (d) $7.5 million of payments due under our notes payable.

After twelve months we have commitments to pay (a) an additional $0.3 million relating to our non-cancelable operating lease commitments.

*SVB Loan Agreement*

On May 7, 2021 (the "Effective Date"), we entered into a Loan and Security Agreement (the "Loan") with SVB for an aggregate principal amount of up to $25.0 million. The Loan bears interest at 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 Loan is secured by all of our tangible assets. The Loan matures on May 1, 2025. The Loan requires monthly interest-only payments until June 1, 2022. The interest-only period can be extended to June 1, 2023, upon the occurrence of a milestone event. Upon the end of the interest-only period, we will make regular monthly amortizing payments of principal and interest through the maturity date. The Loan indicates a prepayment fee of 1.0% to 3.0%, as follows: (i) prepayment fee of 3.0% of the principal balance made on or prior to the first anniversary of the Effective Date; (ii) prepayment fee of 2.0% of the principal balance made on or prior to the second anniversary of the Effective Date; or (iii) prepayment fee of 1.0% of the principal balance made on or prior to the third anniversary of the Effective Date. The Loan also provides for a final payment in an amount equal to the original aggregate principal amount of the 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 is due on the earliest to occur of the loan maturity date, the repayment of the loan in full or the termination of the Loan Agreement.

The initial tranche of the Loan, in the amount of $7.5 million was received on May 7, 2021. At our option, we have the ability to draw down the remaining $17.5 million in gross proceeds in two tranches over the next two years based upon the achievement of several milestones in accordance with the terms of the Loan.

On September 29, 2021, we executed the First Amendment to the Loan and Security Agreement (the "Amendment") with SVB. In accordance with the Amendment, we must maintain a collateralized money market account in the amount of $7,875,000. We have recorded this amount as restricted cash. This account must be maintained until the Release Event occurs, which was defined as when we have received approval by the FDA of Mydcombi and have achieved the minimum equity raise under the terms of the amended agreement, on or prior to November 30, 2021.

On October 25, 2021, we announced the reclassification of Mydcombi as a drug-device combination product by the FDA in a CRL received on October 22, 2021. We have prepared the necessary documents for expedited filing of the NDA resubmission for Mydcombi in response to the CRL. 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. On February 8, 2022, we issued a press release announcing that we successfully completed a Type A meeting with the FDA related to the refiling of the NDA for Mydcombi. Following the Type A meeting, we reached alignment on the path forward toward an NDA resubmission with the FDA. We expect to file the NDA resubmission during the third quarter of 2022.

On November 30, 2021, we entered into a Waiver Agreement, pursuant to which SVB waived the existing default related to the failure to comply with the minimum equity raise financial covenant set forth in the Loan. However, the Loan is currently callable by SVB, due to having not yet received FDA approval of Mydcombi.

In connection with the Loan, we 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. We incurred $66,618 of debt issuance costs.

*Going Concern*

As of December 31, 2021, we had unrestricted cash and cash equivalents of approximately $19.5 million and an accumulated deficit of approximately $90.2 million. For the years ended December 31, 2021 and 2020, we incurred net losses of approximately $12.8 million and $19.8 million, respectively, and used cash in operations of approximately $20.9 million and $6.4 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.

On March 3, 2022, we raised approximately $15 million through the issuance and sale of 3,000,000 shares of common stock, pre-funded warrants to purchase an aggregate of 1,870,130 shares of common stock and warrants to purchase an aggregate of 4,870,130 shares of common stock at an exercise price of $3.54 per share.

Subsequent to December 31, 2021, we received approximately $0.9 million in gross and net proceeds from the sale of 252,449 shares of our common stock pursuant to an at-the-market offering.

**Risks and Uncertainties**

Due to the COVID-19 pandemic, there have been delays in trial enrollment as a result of supply chain issues with our third party suppliers, which in turn diminished our inventory supply.

The short- and long-term worldwide implications of Russia's invasion of Ukraine are difficult to predict at this time. The imposition of sanctions on Russia by the United States or other countries and possible counter sanctions by Russia, and the resulting economic impacts on oil prices and other materials and goods, could affect the price of materials used in the manufacture of our product candidates. If the price of materials used in the manufacturing of our product candidates increase, that would adversely affect our business and the results of our operations.

**Critical Accounting Estimates**

The following represent our most critical accounting estimates

*Use of Estimates*

Preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ("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.

*Deferred License Fee*

We enter into license agreements which provides for the receipt of non-refundable, upfront licensing payments. These payments are recorded as deferred license fees and will be earned and recognized as revenue upon the satisfaction of performance obligations. See Revenue Recognition below for additional details.

*Deferred License Costs*

We enter into license agreements which provides for payment of license costs in connection with our receipt of license fees. These payments are recorded as deferred license costs and will be recorded as an expense when the related license fee revenue is recognized.

*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" ("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" ("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.

**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.**

Smaller reporting companies such as us 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 (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, 2021 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, 2021.

**Management's Report on Internal Control over Financial Reporting**

Our management, including our principal executive officer and principal financial 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 officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2021, 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 officer have concluded that our internal control over financial reporting was effective as of December 31, 2021.

**Changes in Internal Control over Financial Reporting**

There has been no change in our internal control over financial reporting that occurred during the fourth quarter of 2021 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 2022 Annual Meeting of Stockholders currently scheduled to be held on June 16, 2022, 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 proxy statement related to the 2022 Annual Meeting of Stockholders.

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.eyenoviabio.com.

The information required by this Item concerning our executive officers is incorporated by reference from the section captioned "Executive Officers" contained in our proxy statement related to the 2022 Annual Meeting of Stockholders.

The information required by this Item concerning compliance with Section 16(a) of the Exchange Act is incorporated by reference from the section of the 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 the proxy statement for the 2022 Annual Meeting of Stockholders.

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

The following table provides information as of December 31, 2021 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 | 1,021.222 | $ 2.96 | 29,008 |
| Amended and Restated 2018 Omnibus Stock Incentive Plan | 3,483,901 | 4.01 | 671,733 |
| Equity compensation plans not approved by security holders | — | — | — |
| Total | 4,505,123 | $ 3.78 | 700,741 |

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 the proxy statement for the 2022 Annual Meeting of Stockholders.

**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 the proxy statement for the 2022 Annual Meeting of Stockholders.

**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 2022 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. Exhibit 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 Michael Rowe. | 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 | 333-23378 | 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 | 10-Q | 001-38365 | 10.3 | August 12, 2021 |
| 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 | -- | -- | -- | Filed herewith |
| 10.23 | Addendum to Executive Employment Agreement, dated March 10, 2022, by and between the Company and Tsontcho Ianchulev | -- | -- | -- | Filed herewith |
| 10.24 | Addendum to Executive Employment Agreement, dated March 10, 2022, by and between the Company and John Gandolfo | -- | -- | -- | Filed herewith |
| 10.25 | Addendum to Executive Employment Agreement, dated March 10, 2022, by and between the Company and Michael Rowe | -- | -- | -- | 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, 2021 and 2020; (ii) Statements of Operations for the Years Ended December 31, 2021 and 2020; (iii) Statements of Changes in Stockholders' Equity for the Years Ended December 31, 2021 and 2020; (iv) Statements of Cash Flows for the Years Ended December 31, 2021 and 2020; 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.
\# Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10).

**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 30, 2022

By: /s/ Tsontcho Ianchulev
Tsontcho Ianchulev
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/ Tsontcho Ianchulev<br>Tsontcho Ianchulev | Chief Executive Officer<br>(Principal Executive Officer) and Director | March 30, 2022 |
| /s/ John Gandolfo<br>John Gandolfo | Chief Financial Officer<br>(Principal Financial and Accounting Officer) | March 30, 2022 |
| /s/ Stephen Benjamin<br>Stephen Benjamin | Director | March 30, 2022 |
| /s/ Julia A. Haller<br>Julia A. Haller | Director | March 30, 2022 |
| /s/ Rachel Jacobson<br>Rachel Jacobson | Director | March 30, 2022 |
| /s/ Curt H. LaBelle<br>Curt H. LaBelle | Director | March 30, 2022 |
| /s/ Kenneth B. Lee, Jr.<br>Kenneth B. Lee, Jr. | Director | March 30, 2022 |
| /s/ Charles E. Mather IV<br>Charles E. Mather IV | Director | March 30, 2022 |
| /s/ Anthony Y. Sun<br>Anthony Y. Sun | Director | March 30, 2022 |

**EYENOVIA, INC.**

**INDEX TO FINANCIAL STATEMENTS**

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders 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, 2021 and 2020, the related statements of operations, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2021 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, 2021 and 2020, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2021, 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 for a reasonable period of time, which is considered to be one year from the issuance of the financial statements. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

**Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our 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 30, 2022

**EYENOVIA, INC.**

**Balance Sheets**

| | December 31, 2021 | December 31, 2020 |
|---|---|---|
| **Assets** | | |
| Current Assets: | | |
| Cash and cash equivalents | $ 19,461,850 | $ 28,371,828 |
| Deferred license costs | — | 1,600,000 |
| License fee and expense reimbursements receivable | 1,805,065 | 2,966,039 |
| Prepaid expenses and other current assets | 734,942 | 453,478 |
| Total Current Assets | 22,001,857 | 33,391,345 |
| Restricted cash | 7,875,000 | — |
| Property and equipment, net | 1,271,225 | 396,380 |
| Security and equipment deposits | 510,976 | 119,035 |
| Total Assets | $ 31,659,058 | $ 33,906,760 |
| **Liabilities and Stockholders' Equity** | | |
| Current Liabilities: | | |
| Accounts payable | $ 1,614,104 | $ 1,461,665 |
| Accrued compensation | 1,543,618 | 1,150,672 |
| Accrued expenses and other current liabilities | 845,719 | 1,480,692 |
| Deferred rent - current portion | 18,685 | 7,809 |
| Deferred license fee | — | 14,000,000 |
| Notes payable - current portion, net | 7,150,368 | 97,539 |
| Total Current Liabilities | 11,172,494 | 18,198,377 |
| Deferred rent - non-current portion | 19,949 | 38,684 |
| Notes payable - non-current portion, net | — | 365,814 |
| Total Liabilities | 11,192,443 | 18,602,875 |
| 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, 2021 and 2020, respectively | — | — |
| Common stock, $0.0001 par value, 90,000,000 shares authorized; 28,426,616 and 24,978,585 shares issued and outstanding as of December 31, 2021 and 2020, respectively | 2,844 | 2,498 |
| Additional paid-in capital | 110,683,077 | 92,742,306 |
| Accumulated deficit | (90,219,306) | (77,440,919) |
| Total Stockholders' Equity | 20,466,615 | 15,303,885 |
| Total Liabilities and Stockholders' Equity | $ 31,659,058 | $ 33,906,760 |

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

**EYENOVIA, INC.**

**Statements of Operations**

| | For the Years Ended December 31, | |
|---|---|---|
| | **2021** | **2020** |
| **Operating Income** | | |
| Revenue | $ 14,000,000 | $ 2,000,000 |
| Cost of revenue | (1,600,000) | (800,000) |
| Gross Profit | 12,400,000 | 1,200,000 |
| | | |
| **Operating Expenses:** | | |
| Research and development | 14,509,525 | 13,363,251 |
| General and administrative | 10,794,158 | 7,625,974 |
| Total Operating Expenses | 25,303,683 | 20,989,225 |
| | | |
| Loss From Operations | (12,903,683) | (19,789,225) |
| | | |
| **Other Income (Expense):** | | |
| Small Business Administration Economic | | |
| Injury Disaster Grant | — | 10,000 |
| Extinguishment of PPP 7(a) loan | 463,353 | — |
| Other income, net | 47,183 | — |
| Interest expense | (387,756) | (17,042) |
| Interest income | 2,516 | 26,400 |
| | | |
| **Net Loss** | $ (12,778,387) | $ (19,769,867) |
| | | |
| Net Loss Per Share - Basic and Diluted | $ (0.49) | $ (0.94) |
| | | |
| Weighted Average Number of Common Shares Outstanding - Basic and Diluted | 26,324,081 | 21,054,706 |

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, 2021 and 2020 | | | | |
|---|---|---|---|---|---|
| | Common Stock | | Additional Paid-In Capital | Accumulated Deficit | Total Stockholders' Equity |
| | Shares | Amount | | | |
| **Balance - January 1, 2020** | 17,100,726 | $ 1,710 | $ 69,409,949 | $(57,671,052) | $ 11,740,607 |
| Issuance of common stock and warrants in private placement [1] | 2,675,293 | 267 | 5,451,475 | — | 5,451,742 |
| Issuance of common stock in public offering [2] | 3,833,334 | 383 | 12,495,325 | — | 12,495,708 |
| Exercise of stock warrants | 1,332,841 | 134 | 2,820,228 | — | 2,820,362 |
| Exercise of stock options | 36,391 | 4 | 82,157 | — | 82,161 |
| Stock-based compensation | — | — | 2,483,172 | — | 2,483,172 |
| Net loss | — | — | — | (19,769,867) | (19,769,867) |
| **Balance - December 31, 2020** | 24,978,585 | 2,498 | 92,742,306 | (77,440,919) | 15,303,885 |
| Issuance of common stock in At the Market offering [3] | 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 [4] | — | — | 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 |

[1] Includes gross proceeds of $5,984,931, less total issuance costs of $533,189.
[2] Includes gross proceeds of $13,800,002, less total issuance costs of $1,304,294.
[3] Includes gross proceeds of $12,785,483, less total issuance costs of $383,564.
[4] Allocated fair value of warrants of $354,539, less allocated issuance costs of $3,149.

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

## EYENOVIA, INC.

## Statements of Cash Flows

| | For the Years Ended December 31, | |
|---|---|---|
| | 2021 | 2020 |
| **Cash Flows From Operating Activities** | | |
| Net loss | $ (12,778,387) | $ (19,769,867) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation | 2,886,102 | 2,483,172 |
| Depreciation of property and equipment | 221,563 | 95,415 |
| Amortization of debt discount | 68,376 | — |
| Gain on forgiveness of PPP 7(a) Loan | (463,353) | — |
| 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 | 423,896 | 218,418 |
| License fee and expense reimbursements receivables | 1,397,924 | (2,966,039) |
| Deferred license costs | 1,600,000 | (1,600,000) |
| Accounts payable | 126,115 | (79,693) |
| Accrued compensation | 392,946 | 233,799 |
| Accrued expenses and other current liabilities | (634,973) | 1,000,612 |
| Deferred license fee | (14,000,000) | 14,000,000 |
| Security and equipment deposits | — | (1,235) |
| Deferred rent | (7,859) | 1,142 |
| **Net Cash Used In Operating Activities** | (20,874,432) | (6,384,276) |
| **Cash Flows From Investing Activities** | | |
| Purchases of property and equipment | (1,226,576) | (261,257) |
| Vendor deposits for property and equipment | (391,941) | — |
| **Net Cash Used In Investing Activities** | (1,618,517) | (261,257) |
| **Cash Flows From Financing Activities** | | |
| Proceeds from sale of common stock and warrants in private placement [1] | — | 5,569,136 |
| Proceeds from sale of common stock in public offering [2] | — | 12,734,002 |
| Issuance of common stock in At the Market Offering- October-November 2021 [3] | 12,401,919 | — |
| Proceeds from exercise of stock warrants | 2,124,904 | 2,820,362 |
| Proceeds from PPP 7(a) loan | — | 463,353 |
| Proceeds from SVB loan | 7,500,000 | — |
| Repayments of notes payable | (705,360) | (475,216) |
| Payment of offering issuance costs | — | (329,038) |
| Payment of loan issuance costs | (66,618) | — |
| Proceeds from exercise of stock options | 203,126 | 82,161 |
| **Net Cash Provided By Financing Activities** | 21,457,971 | 20,864,760 |
| **Net (Decrease) Increase in Cash and Cash Equivalents** | (1,034,978) | 14,219,227 |
| **Cash and cash equivalents - Beginning of Period** | 28,371,828 | 14,152,601 |
| **Cash and cash equivalents - End of Period** | $ 27,336,850 | $ 28,371,828 |

[1] Includes gross proceeds of $5,984,931, less issuance costs of $415,795 deducted directly from the private placement.
[2] Includes gross proceeds of $13,800,002, less issuance costs of $1,066,000 deducted directly from the offering proceeds.
[3] Includes gross proceeds of $12,785,483, less total issuance costs of $383,564.

| | | |
|---|---|---|
| Cash, cash equivalents and restricted cash consisted of the following: | | |
| Cash and cash equivalents | $ 19,461,850 | $ 28,371,828 |
| Restricted cash | 7,875,000 | — |
| | $ 27,336,850 | $ 28,371,828 |
| **Supplemental Disclosure of Cash Flow Information:** | | |
| Cash paid during the periods for: | | |
| Interest | $ 227,171 | $ 13,974 |
| **Supplemental Disclosure of Non-Cash Investing and Financing Activities** | | |
| Purchase of insurance premium financed by note payable | $ 705,360 | $ — |
| Shares withheld from option exercise for employee tax liability | $ 26,324 | $ — |
| Issuance of common stock related to vested restriced stock units | $ 2 | $ — |
| Warrants issued for debt issuance costs | $ 351,390 | $ — |

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

**EYENOVIA, INC.**
**NOTES TO THE FINANCIAL STATEMENTS**
**FOR THE YEARS ENDED DECEMBER 31, 2021 AND 2020**

**Note 1 – Business Organization and Nature of Operations**

Eyenovia, Inc. ("Eyenovia" or the "Company") is a clinical stage ophthalmic company developing a pipeline of advanced therapeutics based on the Company's proprietary microdose array print (MAP™) platform technology. The Company aims to achieve clinical microdosing of next-generation formulations of novel and existing ophthalmic pharmaceutical agents using its high-precision targeted ocular delivery system, branded the Optejet®. Optejet µ-therapeutics have the potential to replace conventional eye dropper delivery and improve safety, tolerability, patient compliance and topical delivery success for ophthalmic eye treatments. In the clinic, the Optejet has demonstrated that its targeted horizontal microdose delivery can achieve a significantly higher rate of successful ocular topical delivery compared to the established rate reported with traditional eye drops (~ 90% vs. ~ 50%). The Company's technology is designed to achieve single-digit µl-volume physiologic drug delivery with up to a 75% reduction in ocular drug and preservative topical dosing and has demonstrated significant improvement in the therapeutic index in drugs used for presbyopia, mydriasis and IOP lowering through six Phase II and Phase III trials. Conventional eye formulations lack high-precision micro-volume delivery and expose the ocular surface to approximately 300% more medication and preservatives than are physiologically indicated leading to clinically recognized ocular and non-ocular side effects. Using the Optejet, the Company is developing the next generation of smart ophthalmic therapeutics which target new indications or new combinations where there are currently none or few drug therapies approved by the U.S. Food and Drug Administration, or the FDA. The Company's microdose therapeutics follow the FDA-designated combination product registration and regulatory process. The Company's 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 FDA CDER for premarket review and approval under new drug applications, or NDAs.

Risks and Uncertainties

Due to the COVID-19 pandemic, there have been delays in trial enrollment as a result of supply chain issues with the Company's third party suppliers, which in turn diminished the Company's inventory supply.

**Note 2 – Summary of Significant Accounting Policies**

Liquidity and Going Concern

As of December 31, 2021, the Company had unrestricted cash and cash equivalents of approximately $19.5 million and an accumulated deficit of approximately $90.2 million. For the years ended December 31, 2021 and 2020, the Company incurred net losses of approximately $12.8 million and $19.8 million, respectively, and used cash in operations of approximately $20.9 million and $6.4 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. 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.

On March 3, 2022, the Company raised approximately $15 million through the issuance and sale of 3,000,000 shares of common stock, pre-funded warrants to purchase an aggregate of 1,870,130 shares of common stock and warrants to purchase an aggregate of 4,870,130 shares of common stock at an exercise price of $3.54 per share. See Note 13 – Subsequent Events – Securities Purchase Agreement.

Subsequent to December 31, 2021, the Company received approximately $0.9 million in gross and net proceeds from the sale of 252,449 shares of its common stock pursuant to the December 2021 Sales Agreement. See Note 11 – Stockholders' Equity - At-The-Market Offering and Note 13 – Subsequent Events – December 2021 Sales Agreement.

**EYENOVIA, INC.**
**NOTES TO THE FINANCIAL STATEMENTS**
**FOR THE YEARS ENDED DECEMBER 31, 2021 AND 2020**

Use of Estimates

Preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ("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, such as the collateralized money market account pursuant to the Loan and Security Agreement, dated May 7, 2021 with Silicon Valley Bank ("SVB"), as amended on September 29, 2021 by the First Amendment to the Loan and Security Agreement. See Note 7 - Notes Payable - Silicon Valley Bank Loan. In connection with this loan, the Company has pledged to establish and maintain a collateralized money market account in the amount of $7,875,000. The restricted cash is classified as non-current because management does not expect the restricted cash to be available to satisfy current liabilities during the next twelve months.

The Company has cash deposits and U.S. treasury bills in financial institutions which, at times, may be in excess of Federal Deposit Insurance Corporation ("FDIC") insurance limits. The Company has not experienced losses in such accounts and periodically evaluates the creditworthiness of its financial institutions. As of December 31, 2021 and 2020, the Company had cash and cash equivalent balances in excess of FDIC insurance limits of $19,211,850 and $28,121,828, respectively.

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, 2021 and 2020.

**EYENOVIA, INC.**
**NOTES TO THE FINANCIAL STATEMENTS**
**FOR THE YEARS ENDED DECEMBER 31, 2021 AND 2020**

Fair Value of Financial Instruments

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

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

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

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

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

The carrying amounts of the Company's financial instruments, such as cash and cash equivalents, 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 ("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.

Deferred License Fee

The Company enters into license agreements which provides for the receipt of non-refundable, upfront licensing payments. These payments are recorded as deferred license fees and will be earned and recognized as revenue upon the satisfaction of performance obligations. See Revenue Recognition below for additional details.

Deferred License Costs

The Company enters into license agreements which provides for payment of license costs in connection with the Company's receipt of license fees. These payments are recorded as deferred license costs and will be recorded as an expense when the related license fee revenue is recognized. See Note 10 – Related Party Transactions for additional details.

**EYENOVIA, INC.**
**NOTES TO THE FINANCIAL STATEMENTS**
**FOR THE YEARS ENDED DECEMBER 31, 2021 AND 2020**

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" ("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" ("ASC 606"). The Company's policy is to recognize amounts allocated to joint operating activities as a reduction in research and development expense.

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

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

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. 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. The Company assesses if these options provide a material right to the customer and if so, they are considered performance obligations.

For upfront license fees, the Company 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.

During 2020, the Company entered into a license agreement (the "Arctic Vision License Agreement") with Arctic Vision (Hong Kong) Limited ("Arctic Vision") and a license agreement (the "Bausch License Agreement") with Bausch Health Companies, Inc. ("Bausch Health"). 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 ("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.

**EYENOVIA, INC.**
**NOTES TO THE FINANCIAL STATEMENTS**
**FOR THE YEARS ENDED DECEMBER 31, 2021 AND 2020**

*Upfront License Fees*

Under the terms of the Arctic Vision License Agreement, in August 2020, the Company received a non-refundable, upfront payment of $4.0 million, 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, the Company recognized the deferred license fees during the year ended December 31, 2021. 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 up to a total of $43.75 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, which could result in payments of up to $39.75 million (including aggregate potential milestone revenues related to the filing of Marketing Authorization Applications (“MAA”s) of approximately $15.23 million and the receipt of regulatory approvals of approximately $24.52 million), and development costs of up to $4.0 million. In December 2020, the Company satisfied a milestone performance obligation to file an MAA for a MicroStat product in the United States of America (the “United States”) whereby the Company earned and recognized $2.0 million of milestone revenues. The Company currently anticipates the remaining milestone related performance obligations to be achieved between late 2023 and late 2025.

*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, 2021. The Company will pay a percentage in the range from 30 to 40 percent 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 Health may develop and commercialize the Bausch Licensed Product in the Licensed Territory. Bausch Health 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.

**EYENOVIA, INC.**
**NOTES TO THE FINANCIAL STATEMENTS**
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*Upfront License Fees*

In connection with the Bausch License Agreement, Bausch Health paid the Company a non-refundable, upfront payment of $10.0 million on October 14, 2020. The Company recorded this payment as a deferred license fee until certain trial data were fully submitted to Bausch Health and clinical trial supervisory oversight was transferred to Bausch Health, permitting Bausch Health to assume supervisory oversight of the ongoing MicroPine study (the CHAPERONE study). 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.

*Milestone Payments*

Bausch Health 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 during the year ended December 31, 2021. 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 Health 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 10$^{th}$ 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 during the year ended December 31, 2021.

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.

**EYENOVIA, INC.**
**NOTES TO THE FINANCIAL STATEMENTS**
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Net Loss Per Common Share

Basic net loss per common share is computed by dividing net loss by the weighted average number of common shares 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 securities are excluded from the calculation of weighted average dilutive common shares because their inclusion would have been anti-dilutive:

| | December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Warrants | 1,217,715 | 2,011,313 |
| Options | 4,377,398 | 3,427,705 |
| Restricted stock units | 41,778 | 104,083 |
| Total potentially dilutive shares | 5,636,891 | 5,543,101 |

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

In July 2017, the FASB issued Accounting Standards Update ("ASU") 2017-11 "Earnings Per Share (Topic 260) and Derivatives and Hedging (Topic 815) - Accounting for Certain Financial Instruments with Down Round Features" ("ASU 2017-11"). Equity-linked instruments, such as warrants and convertible instruments may contain down round features that result in the strike price being reduced on the basis of the pricing of future equity offerings. Under ASU 2017-11, a down round feature will no longer require a freestanding equity-linked instrument (or embedded conversion option) to be classified as a liability that is remeasured at fair value through the income statement (i.e. marked-to-market). However, other features of the equity-linked instrument (or embedded conversion option) must still be evaluated to determine whether liability or equity classification is appropriate. Equity classified instruments are not marked-to-market. For earnings per share ("EPS") reporting, the ASU requires companies to recognize the effect of the down round feature only when it is triggered by treating it as a dividend and as a reduction of income available to common shareholders in basic EPS. The amendments in this ASU are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. This standard, which the Company adopted on January 1, 2020, did not have a material impact on the Company's financial position, results of operations, or cash flows.

In August 2018, the FASB issued Accounting Standards Update ("ASU") No. 2018-13 "Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement" ("ASU 2018-13"). The amendments in ASU 2018-13 modify the disclosure requirements on fair value measurements based on the concepts in the FASB Concepts Statement, including the consideration of costs and benefits. The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. The amendments are effective for fiscal years beginning after December 15, 2020. The Company adopted ASU 2018-13 effective January 1, 2021. This standard did not have a material impact on the Company's financial position, results of operations or cash flow.

In March 2020, the FASB issued ASU 2020-03 "Codification Improvements to Financial Instruments" ("ASU 2020-03"). ASU 2020-03 improves and clarifies various financial instruments topics. ASU 2020-03 includes seven different issues that describe the areas of improvement and the related amendments to GAAP, intended to make the standards easier to understand and apply by eliminating inconsistencies and providing clarifications. The Company adopted ASU 2020-03 upon issuance, which did not have a material impact on the Company's financial position, results of operations or cash flow.

**EYENOVIA, INC.**
**NOTES TO THE FINANCIAL STATEMENTS**
**FOR THE YEARS ENDED DECEMBER 31, 2021 AND 2020**

Recently Issued Accounting Standards

In February 2016, the FASB issued ASU 2016-02 "Leases (Topic 842)" ("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. For leases with a term of 12 months or less, a lessee is permitted to make an accounting policy election by class of underlying asset not to recognize lease assets and lease liabilities. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. ASU 2016-02, as amended, is now effective for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. The FASB issued ASU 2019-01 "Leases (Topic 842) Codification Improvements" in March 2019 and ASU 2018-10 "Codification Improvements to Topic 842, Leases" and ASU 2018-11 "Leases (Topic 842) Targeted Improvements" in July 2018, and ASU 2018-20 "Leases (Topic 842) - Narrow Scope Improvements for Lessors" in December 2018. ASU 2019-01, ASU 2018-10 and ASU 2018-20 provide certain amendments that affect narrow aspects of the guidance issued in ASU 2016-02. ASU 2018-11 allows all entities adopting ASU 2016-02 to choose an additional (and optional) transition method of adoption, under which an entity initially applies the new leases standard at the adoption date and recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. In June 2020, the FASB issued ASC 2020-05, which defers the effective date for non-public and emerging growth companies until fiscal years ended after December 15, 2021 and interim periods within fiscal years beginning after December 15, 2022. The Company expects that the adoption of this ASU will have 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 December 2019, the FASB issued ASU 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes," which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. ASU 2019-12 is effective for fiscal years beginning after December 15, 2021. The Company does not expect the adoption of ASU 2019-12 to have a material impact financial position, results of operations, and cash flows.

On May 3, 2021, the Financial Accounting Standards Board (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. Early adoption is permitted, including adoption in an interim period. If an issuer elects to early adopt the new standard in an interim period, the guidance should be applied as of the beginning of the fiscal year that includes that interim period. The Company does not expect the adoption of ASU 2021-04 to have a material impact on its financial position, results of operations, and cash flows.

**EYENOVIA, INC.**
**NOTES TO THE FINANCIAL STATEMENTS**
**FOR THE YEARS ENDED DECEMBER 31, 2021 AND 2020**

**Note 3 – Prepaid Expenses and Other Current Assets**

As of December 31, 2021 and 2020, prepaid expenses and other current assets consisted of the following:

| | December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Payroll tax receivable | $ 343,785 | $ 151,942 |
| Prepaid insurance expenses | 171,370 | 110,094 |
| Prepaid general and administrative expenses | 71,375 | — |
| Prepaid board of directors fees | 66,250 | 68,250 |
| Prepaid patent expenses | 32,797 | — |
| Prepaid rent and security deposit | 32,254 | 25,004 |
| Prepaid conference expenses | 12,586 | 29,403 |
| Other | 4,525 | 11,734 |
| Prepaid licenses and subscriptions | — | 57,051 |
| Total prepaid expenses and other current assets | $ 734,942 | $ 453,478 |

**Note 4 – Property and Equipment, Net**

As of December 31, 2021 and 2020, property and equipment consisted of the following:

| | December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Equipment | $ 854,060 | $ 435,521 |
| Equipment not yet placed in service | 254,864 | — |
| Leasehold improvements | 490,709 | 137,765 |
| | 1,599,633 | 573,286 |
| Less: accumulated depreciation and amortization | (328,408) | (176,906) |
| Property and equipment, net | $ 1,271,225 | $ 396,380 |

Depreciation expense was $221,563 and $95,415 for the years ended December 31, 2021 and 2020, respectively, of which $211,604 and $67,595 was included within research and development expenses and $9,959 and $27,820 was included in general and administrative expenses in the statements of operations for the years ended December 31, 2021 and 2020, respectively.

In December 2021, the Company sold equipment used in the CHAPERONE trial with a book value of $130,168 to Bausch Health. The gross proceeds of the sale were $185,362, which resulted in a gain on sale of $55,194.

As of December 31, 2021, the Company had $391,941 of outstanding deposits for equipment purchases which are included within Security and Equipment Deposits in the accompanying balance sheet.

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**Note 5 – Accrued Expenses and Other Current Liabilities**

As of December 31, 2021 and 2020, accrued expenses and other current liabilities consisted of the following:

| | December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Accrued research and development expenses | $ 436,840 | $ 348,254 |
| Accrued consulting and professional services | 250,000 | 235,355 |
| Accrued interest | 94,792 | 3,068 |
| Other | 42,407 | 1,627 |
| Credit card payable | 20,000 | 50,002 |
| Accrued franchise tax | 1,680 | 32,480 |
| Accrued licensing fees | — | 804,447 |
| Accrued expense reimbursements | — | 5,459 |
| Total accrued expenses and other current liabilities | $ 845,719 | $ 1,480,692 |

**Note 6 – Accrued Compensation**

As of December 31, 2021 and 2020, accrued compensation consisted of the following:

| | December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Accrued bonus expenses | $ 1,245,795 | $ 938,873 |
| Accrued payroll expenses | 297,823 | 211,799 |
| Total accrued compensation | $ 1,543,618 | $ 1,150,672 |

**Note 7 – Notes Payable**

As of December 31, 2021 and 2020, notes payable consisted of the following:

| | December 31, 2021 | | | December 31, 2020 | | |
|---|---|---|---|---|---|---|
| | Notes Payable | Debt Discount | Net | Notes Payable | Debt Discount | Net |
| Paycheck Protection Program loan | $ — | $ — | $ — | $ 463,353 | $ — | $ 463,353 |
| Silicon Valley Bank loan | 7,500,000 | (349,632) | 7,150,368 | — | — | — |
| Total | 7,500,000 | (349,632) | 7,150,368 | 463,353 | — | 463,353 |
| Less: Current portion | | | | | | |
| Paycheck Protection Program loan | — | — | — | (97,539) | — | (97,539) |
| Silicon Valley Bank loan | (7,500,000) | 349,632 | (7,150,368) | — | — | — |
| Notes Payable, Non-Current | $ — | $ — | $ — | $ 365,814 | $ — | $ 365,814 |

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 $705,360. The note accrued interest at a rate of 2.96% per year and matured on November 24, 2021.The note payable was repaid during the year ended December 31, 2021.

**EYENOVIA, INC.**
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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 (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 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 has been reversed from interest expense.

Silicon Valley Bank Loan

On May 7, 2021 (the "Effective Date"), the Company entered into a Loan and Security Agreement (the "Loan") with Silicon Valley Bank ("SVB") for an aggregate principal amount of up to $25.0 million. The Loan bears interest at 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 Loan is secured by all of the Company's tangible assets. The Loan matures on May 1, 2025. The Loan requires monthly interest-only payments until June 1, 2022. The interest-only period can be extended to June 1, 2023, upon the occurrence of a milestone event. Upon the end of the interest-only period, the Company will make regular monthly amortizing payments of principal and interest through the maturity date. The Loan indicates a prepayment fee of 1.0% to 3.0%, as follows: i) prepayment fee of 3.0% of the principal balance made on or prior to the first anniversary of the Effective Date; ii) prepayment fee of 2.0% of the principal balance made on or prior to the second anniversary of the Effective Date; or iii) prepayment fee of 1.0% of the principal balance made on or prior to the third anniversary of the Effective Date. The Loan also provides for a final payment in an amount equal to the original aggregate principal amount of the 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 is due on the earliest to occur of the loan maturity date, the repayment of the loan in full or the termination of the Loan Agreement. The Company is accreting the final payment as accrued interest over the term of the Loan.

The initial tranche of the Loan, in the amount of $7.5 million was received by the Company on May 7, 2021. At the Company's option, the Company has the ability to draw down the remaining $17.5 million in gross proceeds in two tranches over the next two years based upon the achievement of several milestones in accordance with the terms of the Loan.

On September 29, 2021, the Company and SVB executed the First Amendment to the Loan and Security Agreement (the "Amendment"). In accordance with the Amendment, the Company must maintain a collateralized money market account in the amount of $7,875,000. The Company has recorded this amount as restricted cash. See Note 2 - Summary of Significant Accounting Policies - Cash, Cash Equivalents and Restricted Cash. This account must be maintained until the Release Event occurs, which was defined as when the Company has received approval by the FDA of Mydcombi and has achieved the minimum equity raise under the terms of the amended agreement, on or prior to November 30, 2021.

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. The Company has prepared the necessary documents for expedited resubmission of the NDA for Mydcombi in response to the CRL. 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 has been fully classified as a current note payable. On February 8, 2022, the Company issued a press release announcing that it successfully completed a Type A meeting with the FDA related to the filing of the NDA resubmission for Mydcombi. Following the Type A meeting, the Company and the FDA reached alignment on the path forward toward an NDA resubmission. The Company expects to file the NDA resubmission during the third quarter of 2022.

On November 30, 2021, the Company entered into a Waiver Agreement, pursuant to which SVB waived the Company's existing default related to the Company's failure to comply with the minimum equity raise financial covenant set forth in the Loan. However, the Loan is currently callable by SVB due to the Company having not yet received FDA approval of Mydcombi.

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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 and are being amortized over the four-year term of the note.

During the year ended December 31, 2021, the Company recorded interest expense relating to the Loan of $317,333, including amortization of debt discount of $68,376.

**Note 8 – Income Taxes**

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

| | For The Years Ended December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Deferred tax provision (benefit): | | |
| Federal | (1,248,043) | (3,797,052) |
| State and local | (2,358,623) | (434,082) |
| | (3,606,666) | (4,231,134) |
| Change in valuation allowance | 3,606,666 | 4,231,134 |
| 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, | |
|---|---|---|
| | 2021 | 2020 |
| Federal statutory rate | (21.0)% | (21.0)% |
| State tax rate, net of federal benefit | (7.3)% | (0.1)% |
| Permanent differences | 4.3 % | 0.5 % |
| Research & development tax credits | (0.6)% | (1.4)% |
| Prior period adjustments and other | 0.2 % | 0.6 % |
| Rate changes | (3.8)% | 0.0 % |
| Change in valuation allowance | 28.2 % | 21.4 % |
| Effective income tax rate | 0.0 % | 0.0 % |

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Deferred tax assets consist of the following:

| | For The Years Ended December 31, | |
|---|---|---|
| | 2021 | 2020 |
| Net operating loss carry forwards | $ 17,415,488 | $ 12,972,865 |
| Stock-based compensation | 2,070,759 | 1,385,554 |
| Intangible assets | 531,454 | 409,705 |
| Research and development tax credits | 605,919 | 1,861,938 |
| Deferred tax assets, gross | 20,623,620 | 16,630,062 |
| Property and equipment | (463,442) | (76,550) |
| Deferred tax assets, net before allowance | 20,160,178 | 16,553,512 |
| Valuation allowance | (20,160,178) | (16,553,512) |
| Deferred tax assets, net | $ — | $ — |

As of December 31, 2021, the Company had approximately $72,000,000 of domestic federal net operating loss carryforwards ("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 $61,200,000 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, 2021, the Company had approximately $27,200,000 of state NOLs and $7,400,000 of local NOLs. The state NOLs expire in 2040, while the local NOLs have no expiration date.

The Company has assessed the likelihood that deferred tax assets will be realized in accordance with the provisions of ASC 740 "Income Taxes Accounting" ("ASC 740"). ASC 740 requires that such a review considers all available positive and negative evidence, including the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies. 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. After the performance of such reviews as of December 31, 2021 and 2020, 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, 2021 and 2020. 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, 2021 and 2020. No tax related interest or penalties were incurred during the years ended December 31, 2021 and 2020. The Company's federal, state and local income tax returns beginning with the year ended December 31, 2018 remain subject to examination.

**Note 9 – Commitments and Contingencies**

Employment Agreements

Effective February 15, 2019, the Company entered into at-will executive employment agreements (the "Executive Employment Agreements") with Tsontcho Ianchulev, its Chief Executive Officer and Chief Medical Officer, John Gandolfo, its Chief Financial Officer, and Michael Rowe, its Chief Commercial Officer. Mr. Rowe's Executive Employment Agreement was amended on February 1, 2021 to provide for his new role at the Company. In addition, on February 14, 2022, the Compensation Committee of the Board approved amendments to the Executive Employment Agreements to provide for twelve months of severance pay for each of the executive officers. See Note 13 – Subsequent Events – Employment Agreement Addendums for details regarding further amendments to the Executive Employment Agreements.

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Prior to the amendments to the Executive Employment Agreements, each of the Executive Employment Agreements provided 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 Executive 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 three months of his or her then-current base salary (currently estimated at approximately $332,750 in the aggregate), and (ii) a reimbursement for health insurance benefits under COBRA for the executive and his or her spouse and dependents for a period of three months or until the executive becomes eligible for comparable insurance benefits from another employer, whichever is earlier.

Prior to the amendments to the Executive Employment Agreements, each of the Executive Employment Agreements also provided that if, within 12 months following any "Corporate Transaction" (as defined in the Executive Employment Agreements) of the Company, the executive's employment is terminated by the Company without Cause or the executive suffers an Involuntary Termination, provided that the executive has signed a full release of all claims, the executive will be entitled to receive, in lieu of what is described in the above paragraph: (i) severance pay equal to 12 months of his or her then-current base salary (currently estimated at approximately $1,331,000 in the aggregate), and (ii) a reimbursement for health insurance benefits under COBRA for the executive and his or her spouse and dependents for a period of 12 months or until the executive becomes eligible for comparable insurance benefits from another employer, whichever is earlier.

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 $119,000.

On January 20, 2020, the Company entered into a lease agreement to lease 660 square feet of office space in Laguna Hills, California. The monthly base rent was $1,234 per month. The lease term was one year. The lease has been renewed each year since. The current renewal term expires on April 30, 2022. The monthly base rent is $1,292 per month. In addition, the Company agreed to lease the adjoining premises as part of the lease extension. The additional office space is 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.

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 (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 expires on August 31, 2023. The security deposit is $4,468.

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 VP of R&D. The lease, as amended, expires on September 14, 2022 and provides for lease payments of $5,404 per month and a security deposit in the amount of $5,404. 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 amounted to $64,848 and $59,724 for the years ended December 31, 2021 and 2020, respectively.

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

| For the Year Ending December 31, | Minimum Lease Payments |
|---|---|
| 2022 | $ 464,452 |
| 2023 | 331,442 |
| | $ 795,894 |

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.

Consulting Agreements

A company of which a member of the Company's Board of Directors is part owner is a party to a consulting agreement with the Company dated July 6, 2017 that provides for the payment of $9,567 per month, and $250 per hour for any additional work, for advisory services performed by such director. The consulting agreement was terminated on September 1, 2020. The director remains on the Board. The Company incurred expenses of $76,536 during the year ended December 31, 2020 related to the agreement which is included within general and administrative expenses on the statements of operations.

Senju License Agreement

During 2015, the Company entered into an exclusive license agreement with Senju (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 and, together, they beneficially own greater than 5% of the Company's common stock.

On April 8, 2020, Eyenovia entered into an amendment (the "Senju License Amendment") to the Senju License Agreement. Pursuant to the Senju License Amendment, the Company can license to any third party the right to research, develop, commercialize, manufacture or use certain products identified below (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 (the "Territory") in the agreement executed by the Company on April 8, 2021. The Senju Licensed Products are those using piezo-print technology in a microdose dispenser with (i) atropine sulfate as its sole active ingredient to treat myopia in humans and (ii) pilocarpine as its sole active ingredient to treat presbyopia in humans.

Pursuant to the Senju License Amendment, the Company must pay Senju (a) a percentage in the range of 30 to 40 percent of revenue on any lump-sum payments the Company receives from the third party, revenue (net of costs) obtained by the Company from contract research and/or development of the Senju Licensed Product in the Territory, and 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 percent of any sales royalty revenue the Company receives

from the third party. Since the Company executed a third-party license prior to April 8, 2021, the 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 (the "Letter Agreement"). Pursuant to the Letter Agreement, the Company will pay a percentage in the range of 30 to 40 percent of certain payments, royalties, or net proceeds received from Arctic Vision in connection with the Arctic Vision License Agreement to Senju.The Senju License Agreement was amended further by the License Amendment 2, effective September 14, 2021 (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 thirty percent to forty percent 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 - 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. The Restated Plan makes certain changes to the Company's 2018 Omnibus Stock Incentive Plan, as amended (the "2018 Plan, as amended"). The Restated Plan increases the number of shares of the Company's common stock reserved for issuance under the 2018 Plan, as amended to 2,950,000 shares. 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. Finally, the Restated Plan made several administrative changes to the 2018 Plan, as amended, including to clarify that awards made under the Restated Plan are intended to be exempt from or comply with Section 409(A) of the Internal Revenue Code of 1986, as amended. The Restated Plan was further amended (the "Amended Restated Plan") on June 30, 2021 to increase the number of shares of the Company's common stock reserved for future issuance under the Restated Plan to 4,200,000 shares. As of December 31, 2021, the number of securities remaining available for future issuance under equity compensation plans was 700,741.

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Warrants

A summary of the warrant activity during the year ended December 31, 2021 is presented below:

| | Number of Warrants | Weighted Average Exercise Price | Weighted Average Remaining Life In Years | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding January 1, 2021 | 2,011,313 | $ 2.43 | | |
| Granted | 91,884 | 4.76 | | |
| Exercised | (885,482) | 2.40 | | |
| Outstanding December 31, 2021 | 1,217,715 | $ 2.69 | 3.7 | $ 1,667,925 |
| | | | | |
| Exercisable December 31, 2021 | 1,217,715 | $ 2.69 | 3.7 | $ 1,667,925 |

The following table presents information related to warrants as of December 31, 2021:

| Warrants Outstanding | | Warants Exercisable | |
|---|---|---|---|
| Exercise Price | Outstanding Number of Warrants | Weighted Average Remaining Life In Years | Exercisable Number of Warrants |
| $2.4696 | 909,451 | 3.2 | 909,451 |
| $2.7240 | 216,380 | 3.2 | 216,380 |
| $4.7600 | 91,884 | 9.3 | 91,884 |
| | 1,217,715 | 3.7 | 1,217,715 |

During the year ended December 31, 2021, warrants for the purchase of 885,482 shares of the Company's common stock with exercise prices between $2.058 and $2.4696 per share, respectively, were exercised for aggregate proceeds of approximately $2.1 million.

Securities Purchase Agreement

On March 24, 2020, the Company closed on a private placement of approximately $6.0 million of Units. Each Unit consists of (i) one share of the Company's common stock, (ii) a one-year warrant to purchase 0.5 of a share of common stock ("Class A Warrant"), and (iii) a five-year warrant to purchase 0.75 of a share of common stock ("Class B Warrant") (collectively, the Class A Warrants and Class B Warrants, the "Warrants"). The Units were sold to the public at a price of $2.21425 per Unit and to certain directors and executive officers at a price of $2.42625 per Unit. The Company generated approximately $5.45 million of net proceeds in the offering after deducting placement agent fees and offering expenses of $0.53 million. In the offering, the Company issued an aggregate of 2,675,293 shares of common stock, Class A Warrants to purchase up to 1,337,659 shares of common stock, and Class B Warrants to purchase up to 2,006,495 shares of common stock. The exercise price of the Class A Warrants issued to the public is $2.058 per share and the exercise price of the Class A Warrants issued to the directors and officers is $2.27 per share. The exercise price of the Class B Warrants issued to the public is $2.4696 per share and the exercise price of the Class B Warrants issued to the directors and officers is $2.724 per share. See "Warrants" above for additional details.

In connection with the private placement, on March 23, 2020, the Company also entered into a Registration Rights Agreement with the investors. Pursuant to the Registration Rights Agreement, the Company agreed to file with the SEC, no later than 30 days following the date on which the Company filed its Form 10-¬K for the year ended December 31, 2019 with the SEC, a registration statement on Form S-3 covering the shares of common stock issued in the offering and the shares of common stock underlying the Warrants. The Company timely filed the registration statement on Form S-3 (Registration Statement No. 333¬237790), which was declared effective on May 13, 2020 and remains in effect.

**EYENOVIA, INC.**
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Underwritten Public Offering

On August 19, 2020, the Company entered into an Underwriting Agreement (the "Underwriting Agreement") with several underwriters (the "Underwriters") in connection with the public offering (the "Offering") of 3,333,334 shares of the Company's common stock at a price of $3.60 per share, less underwriting discounts and commissions. In addition, pursuant to the terms of the Underwriting Agreement, the Company granted the Underwriters a 30-day option to purchase up to an additional 500,000 shares of the Company's common stock at the same price. The Underwriting Agreement contains customary representations, warranties and covenants of the Company and also provides for customary indemnification by the Company and the Underwriters against certain liabilities and customary contribution provisions in respect of those liabilities.

The closing of the Offering occurred on August 21, 2020. At closing, the Company issued 3,833,334 shares of common stock and received net proceeds of approximately $12.5 million after deducting underwriting discounts and commissions and offering expenses of approximately $1.2 million.

The Offering was made pursuant to the Company's effective registration statement on Form S-3 (Registration Statement No. 333-229365), including the prospectus dated February 12, 2019, as supplemented by the prospectus supplement dated August 19, 2020.

Stock-Based Compensation Expense

The Company records stock-based compensation expense related to stock options and restricted stock units ("RSUs"). For the years ended December 31, 2021 and 2020, the Company recorded expense of $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) and $2,483,172 ($1,350,894 of which was included within research and development expenses and $1,132,278 was included within general and administrative expenses on the statements of operations), respectively.

Restricted Stock Units

A summary of the restricted stock units activity during the year ended December 31, 2021 is presented below:

| | Number of RSUs | Weighted Average Exercise Price |
|---|---|---|
| RSUs non-vested January 1, 2021 | 104,083 | $ 3.84 |
| Granted | 49,964 | 3.59 |
| Vested | (105,306) | 3.86 |
| Forfeited | (6,963) | 3.59 |
| RSUs non-vested December 31, 2021 | 41,778 | $ 3.59 |

On September 11, 2020, the Company granted members of its Board of Directors an aggregate of 43,728 RSUs under the Restated Plan. Each RSU is subject to settlement into one share of the Company's common stock. The RSUs vested on the earlier of (i) the one-year anniversary of the date of grant and (ii) the date of the 2021 annual stockholders meeting, subject to the grantee remaining on the Board until then. The RSUs had a grant date fair value of $150,000, which will be recognized over the vesting period.

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) 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.

As of December 31, 2021, there was $121,875 of unrecognized stock-based compensation expense related to RSUs which will be recognized over a weighted average period of 0.9 years.

**EYENOVIA, INC.**
**NOTES TO THE FINANCIAL STATEMENTS**
**FOR THE YEARS ENDED DECEMBER 31, 2021 AND 2020**

At-The-Market Offering

*May 2021 Sales Agreement*

On May 14, 2021, the Company entered into a Sales Agreement (the "May 2021 Sales Agreement") with SVB Leerink LLC ("SVB Leerink") 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 Leerink as its sales agent. Subject to the terms and conditions of the May 2021 Sales Agreement, SVB Leerink 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 Leerink 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 Leerink a commission equal to three percent (3.0)% of the gross sales proceeds of any common stock sold through SVB Leerink 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 (the "December 2021 Sales Agreement") with SVB Leerink 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 Leerink as its sales agent (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 (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 Leerink 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 Leerink 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 Leerink a commission equal to three percent (3.0)% of the gross sales proceeds of any common stock sold through SVB Leerink under the December 2021 Sales Agreement, and also has provided SVB Leerink with certain indemnification rights. The Company did not sell any shares of its Common Stock pursuant to the December 2021 Sales Agreement during the fiscal year ended December 31, 2021.

Stock Option Exercises

During the year ended December 31, 2021, stock options for the purchase of an aggregate of 121,261 shares of common stock, with exercise prices ranging from $1.95 to $3.11 per share, were exercised. One of the exercises was a cashless exercise, whereby 13,675 shares were withheld and not issued, to cover the cost to exercise and payroll taxes. Consequently, the exercises resulted in the issuance of 107,586 shares of common stock and the receipt of $203,125 of cash proceeds.

**EYENOVIA, INC.**
**NOTES TO THE FINANCIAL STATEMENTS**
**FOR THE YEARS ENDED DECEMBER 31, 2021 AND 2020**

Stock Options

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, | |
|---|---|---|
| | 2021 | 2020 |
| Expected term (years) | 5.85 - 10.00 | 5.85 - 10.00 |
| Risk free interest rate | 0.45% - 1.58% | 0.26% -1.32% |
| Expected volatility | 92% - 94% | 96% - 99% |
| 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 does not currently have a sufficient trading history to support its historical volatility calculations. Accordingly, the Company is utilizing an expected volatility figure based on a review of the historical volatility of three 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, 2021 and 2020 was approximately $5.39 and $3.01 per share, respectively.

A summary of the option activity during the year ended December 31, 2021 is presented below:

| | Number of Options | Weighted Average Exercise Price | Weighted Average Remaining Life In Years | Aggregate Intrinsic Value |
|---|---|---|---|---|
| Outstanding, January 1, 2021 | 3,427,705 | $ 3.37 | | |
| Granted | 1,106,107 | 5.39 | | |
| Exercised | (121,261) | 2.07 | | |
| Forfeited | (35,153) | 3.67 | | |
| Outstanding, December 31, 2021 | 4,377,398 | $ 3.89 | 7.6 | $ 3,809,684 |
| | | | | |
| Exercisable, December 31, 2021 | 2,525,368 | $ 3.48 | 6.6 | $ 3,003,992 |

**EYENOVIA, INC.**
**NOTES TO THE FINANCIAL STATEMENTS**
**FOR THE YEARS ENDED DECEMBER 31, 2021 AND 2020**

The following table presents information related to stock options as of December 31, 2021:

| Options Outstanding | | | Options Exercisable | |
|---|---|---|---|---|
| Exercise Price | Outstanding Number of Options | Weighted Average Remaining Life In Years | Exercisable Number of Options |
| $1.24 | 260,000 | 3.2 | 260,000 |
| $1.95 | 567,636 | 5.5 | 567,636 |
| $2.72 | 764,419 | 8.4 | 382,210 |
| $2.74 | 667 | 7.0 | 500 |
| $2.89 | 249,751 | 8.4 | 128,868 |
| $3.11 | 656,078 | 7.6 | 519,514 |
| $3.43 | 58,920 | 8.7 | 24,554 |
| $3.48 | 35,000 | 8.7 | 14,584 |
| $3.59 | 57,918 | — | — |
| $3.71 | 43,000 | 8.6 | 20,306 |
| $4.00 | 2,000 | 6.9 | 2,000 |
| $4.06 | 35,000 | — | — |
| $4.53 | 127,000 | — | — |
| $4.68 | 20,000 | 8.1 | 12,223 |
| $4.81 | 219,000 | — | — |
| $5.10 | 6,000 | 6.7 | 5,833 |
| $5.11 | 1,637 | — | — |
| $5.19 | 16,500 | 6.7 | 16,500 |
| $5.25 | 26,668 | 4.8 | 26,668 |
| $5.77 | 50,000 | 9.0 | 16,667 |
| $6.01 | 652,899 | — | — |
| $6.20 | 300,387 | 6.6 | 300,387 |
| $6.30 | 60,000 | 6.5 | 60,000 |
| $8.72 | 166,918 | 6.3 | 166,918 |
| | 4,377,398 | 6.6 | 2,525,368 |

As of December 31, 2021, there was $5,260,000 of unrecognized stock-based compensation expense related to stock options which will be recognized over a weighted average period of 1.9 years.

**Note 12 – Employee Benefit Plans**

401(k) Plan

In April 2019, the Company adopted the Eyenovia 401(k) Plan (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, 2021 and 2020, the Company recorded expense of $175,352 and $138,785 associated with its matching contributions, respectively.

**EYENOVIA, INC.**
**NOTES TO THE FINANCIAL STATEMENTS**
**FOR THE YEARS ENDED DECEMBER 31, 2021 AND 2020**

**Note 13 – Subsequent Events**

December 2021 Sales Agreement

Subsequent to December 31, 2021, the Company received approximately $0.9 million in gross and net proceeds from the sale of 252,449 shares of its common stock pursuant to the December 2021 Sales Agreement.

Securities Purchase Agreement

On March 3, 2022, the Company entered into a securities purchase agreement (the "Purchase Agreement") with a certain institutional and accredited investor (the "Purchaser"), relating to the issuance and sale of 3,000,000 shares (the "Shares") of common stock, pre-funded warrants (the "Pre-Funded Warrants") to purchase an aggregate of 1,870,130 shares of Common Stock and warrants to purchase an aggregate of 4,870,130 shares of common stock (the "Investor Warrants"), (the "March 2022 Offering").

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 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.

Employment Agreement Addendums

On March 10, 2022, the Compensation Committee of the Board approved amendments to the Executive Employment Agreements (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 (currently estimated at approximately $1,331,000 in the aggregate), 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.

Stock Options

Subsequent to December 31, 2021, the Company issued ten-year stock options to certain employees and consultants to purchase an aggregate of 389,422 shares of common stock of the Company at exercise prices ranging from $3.10 to $3.60 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.

Restricted Stock Units

Subsequent to December 31, 2021, the Company approved to amend the terms of an aggregate amount of 13,926 unvested RSUs issued to certain former directors that had been forfeited on their departure date. Pursuant to the amendment, the unvested RSUs shall continue to vest until the earlier of: (i) twelve months from the date of grant; or (ii) the Company's 2022 annual meeting of stockholders.

# 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, 2021, there were 28,426,616 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, 2021, no shares of our preferred stock were outstanding.

## Stock Awards Available For Issuance

As of December 31, 2021, the Company has an aggregate of 700,741 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 ("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".

**EYENOVIA, INC.**

**NON-EMPLOYEE DIRECTOR COMPENSATION POLICY**

*Effective as of April 1, 2022*

Non-employee members of the board of directors (the "Board") of Eyenovia, Inc. (the "Company") shall receive cash and equity compensation for their service on the Board as set forth in this Non-Employee Director Compensation Policy (this "Policy"). The cash and equity compensation described in this Policy shall be paid or issued, as applicable, automatically and without further action of the Board, to each member of the Board who is not an employee of the Company or any subsidiary of the Company (each, a "Non-Employee Director") who is entitled to receive such cash or equity compensation, unless such Non-Employee Director declines the receipt of such cash or equity compensation by written notice to the Company. This Policy shall remain in effect until it is revised or rescinded by further action of the Board. This Policy may be amended, modified or terminated by the Board at any time in its sole discretion. The terms and conditions of this Policy shall supersede any prior cash and/or equity compensation arrangements for service as a member of the Board between the Company and any of its Non-Employee Directors.

## I. CASH COMPENSATION

A. Annual Retainers. Each Non-Employee Director shall receive an annual retainer of $40,000 for service on the Board.

B. Additional Annual Retainers. In addition, Non-Employee Directors shall receive the following annual retainers, as applicable:

1. Audit Committee. A Non-Employee Director serving as Chair of the Audit Committee shall receive an additional annual retainer of $20,000 for such service. A Non-Employee Director serving as a member other than the Chair of the Audit Committee shall receive an additional annual retainer of $10,000 for such service.

2. Compensation Committee. A Non-Employee Director serving as Chair of the Compensation Committee shall receive an additional annual retainer of $15,000 for such service. A Non-Employee Director serving as a member other than the Chair of the Compensation Committee shall receive an additional annual retainer of $7,500 for such service.

3. Nominating and Corporate Governance Committee. A Non-Employee Director serving as Chair of the Nominating and Corporate Governance Committee shall receive an additional annual retainer of $10,000 for such service. A Non-Employee Director serving as a member other than the Chair of the Nominating and Corporate Governance Committee shall receive an additional annual retainer of $5,000 for such service.

C. Payment of Retainers. The retainers described in Sections I(A) and I(B) shall be earned on a quarterly basis based on a calendar quarter and shall be paid in cash by the Company the first week of each calendar quarter. In the event a Non-Employee Director does not serve as a Non-Employee Director, or in the applicable positions described in Section I(B), for an entire calendar quarter, the retainer paid to such Non-Employee Director shall be considered earned for the calendar quarter it was paid as applicable.

## II. EQUITY COMPENSATION

Non-Employee Directors shall be granted the equity awards described below. The awards described below shall be granted under and shall be subject to the terms and provisions of the Company's Amended and Restated 2018 Omnibus Stock Incentive Plan or any other applicable Company equity incentive plan then maintained by the Company (the "Equity Plan") and shall be granted subject to award agreements, including attached exhibits, in substantially the form previously approved by the Board. All applicable terms of the Equity Plan apply to this Policy as if fully set forth herein, and all grants of stock options and restricted stock units ("RSUs") hereby are subject in all respects to the terms of the Equity Plan and the applicable award agreements. For the avoidance of doubt, the share numbers in Sections II(A) and II(B) shall be subject to adjustment as provided in the Equity Plan.

A. Equity Awards. A Non-Employee Director who will continue to serve as a Non-Employee Director immediately following the annual meeting of the Company's stockholders, shall receive $80,000 in annual equity awards, issued half in options (with an exercise price equal to the closing price of the Company's common stock on the Nasdaq Capital Market on the date of grant), valued under Black Scholes, and half in RSUs (the settlement of such RSUs will be deferred until such Non-Employee Director ceases to be a Director), on the date of such annual meeting. The awards described in this Section II(A) shall be referred to as "Director Awards." Any Non-Employee Director that joins the Board after the annual meeting of stockholders in any given year, but before the next annual meeting of stockholders, shall receive a prorated Director Award with a value calculated by: multiplying (a) $80,000 with (b) a fraction (i) the numerator of which is the number of days such Non-Employee Director has served on the Board prior to the next annual meeting, and (ii) the denominator of which is 365 days.

B. Termination of Employment of Employee Directors. Members of the Board who are employees of the Company or any parent or subsidiary of the Company who subsequently terminate their employment with the Company and any parent or subsidiary of the Company and remain on the Board to the extent that they are otherwise entitled, will receive, after termination of employment with the Company and any parent or subsidiary of the Company, Director Awards as described in Section II(A) above.

C. Terms of Awards Granted to Non-Employee Directors

1. Exercise Price. The per share exercise price of each option granted to a Non-Employee Director shall equal the Fair Market Value (as defined in the Equity Plan) of a share of the Company's common stock on the date the option is granted.

2. Vesting. Unless the Board otherwise determines, each Director Award shall vest in full on the earlier of (1) one year from the date of grant and (2) the date of the next annual meeting of the stockholders of the Company. Unless the Board otherwise determines, any portion of a Director Award which is unvested or unexercisable at the time of a Non-Employee Director's termination of service on the Board as a Non-Employee Director shall be immediately forfeited upon such termination of service and shall not thereafter become vested and exercisable.

3. Term. The maximum term of each stock option granted to a Non-Employee Director hereunder shall be ten (10) years from the date the option is granted.

* * * * *

In no event shall the aggregate grant date fair value (determined in accordance with ASC 718) of (1) equity awards to be granted and (2) any cash compensation paid to any Non-Employee Director exceed $150,000 in any fiscal year.

* * * * *

**Exhibit 10.23**

March 10, 2022

Tsontcho Ianchulev, M.D., M.P.H.

*Re: Addendum to Executive Employment Agreement*

Dear Dr. Ianchulev:

The following Addendum represents a modification to the Executive Employment Agreement dated February 15, 2019 (the "Agreement") between Eyenovia, Inc., a Delaware corporation (the "Company"), and Tsontcho Ianchulev (the "Executive") for the express purpose of modifying the terms contained in the Agreement between the parties with respect to the matters below. To the extent that there is an inconsistency between the terms of this Addendum and the terms of the Agreement, the terms of this Addendum shall control. The Agreement is hereby modified, amended or superseded to the extent indicated:

Section 6(a) of the Agreement is hereby superseded by the following:

SEVERANCE. If Executive's employment is terminated by the Company without "Cause" (as such term is defined in the Plan) or Executive suffers an Involuntary Termination (as defined below), provided such termination is a "separation from service" within the meaning of Treasury Regulation § 1.409A-1(h), and provided further that Executive has signed a full general release of all claims in a form reasonably satisfactory to the Company within thirty (30) days of such termination (or such greater time period as required by applicable law for consideration of an employee waiver), Executive will be entitled to receive (i) severance in a total amount equal to twelve (12) months of his then-current Base Salary, less applicable withholdings (the "Severance") and (ii) if Executive properly and timely elects to continue group health insurance benefits under COBRA, reimbursement for his and his spouse and dependents' applicable COBRA premiums for a period of twelve (12) months or until Executive becomes eligible for comparable insurance benefits from another employer, whichever is earlier. The Severance will be paid over a twelve (12) month period in equal installments on the Company's regular payroll schedule beginning on the first pay period following the date the general release of claims is no longer subject to revocation under applicable law.

The Agreement and this Addendum represent the entire understanding between the parties on the subject matter and may not be modified except in a writing signed by both parties. Furthermore, except as expressly provided for herein, the terms of the Agreement are in full force and effect.

| | |
|---|---|
| TSONTCHO IANCHULEV | EYENOVIA, INC. |
| /s/ Tsontcho Ianchulev<br>Signature | By: /s/ Tsontcho Ianchulev<br>Name: Tsontcho Ianchulev<br>Title: Chief Executive Officer |
| | By: /s/ John Gandolfo<br>Name: John Gandolfo<br>Title: Chief Financial Officer |

**Exhibit 10.24**

March 10, 2022

John Gandolfo

*Re: Addendum to Executive Employment Agreement*

Dear Mr. Gandolfo:

The following Addendum represents a modification to the Executive Employment Agreement dated February 15, 2019 (the "Agreement") between Eyenovia, Inc., a Delaware corporation (the "Company"), and John Gandolfo (the "Executive") for the express purpose of modifying the terms contained in the Agreement between the parties with respect to the matters below. To the extent that there is an inconsistency between the terms of this Addendum and the terms of the Agreement, the terms of this Addendum shall control. The Agreement is hereby modified, amended or superseded to the extent indicated:

Section 6(a) of the Agreement is hereby superseded by the following:

SEVERANCE. If Executive's employment is terminated by the Company without "Cause" (as such term is defined in the Plan) or Executive suffers an Involuntary Termination (as defined below), provided such termination is a "separation from service" within the meaning of Treasury Regulation § 1.409A-1(h), and provided further that Executive has signed a full general release of all claims in a form reasonably satisfactory to the Company within thirty (30) days of such termination (or such greater time period as required by applicable law for consideration of an employee waiver), Executive will be entitled to receive (i) severance in a total amount equal to twelve (12) months of his then-current Base Salary, less applicable withholdings (the "Severance") and (ii) if Executive properly and timely elects to continue group health insurance benefits under COBRA, reimbursement for his and his spouse and dependents' applicable COBRA premiums for a period of twelve (12) months or until Executive becomes eligible for comparable insurance benefits from another employer, whichever is earlier. The Severance will be paid over a twelve (12) month period in equal installments on the Company's regular payroll schedule beginning on the first pay period following the date the general release of claims is no longer subject to revocation under applicable law.

The Agreement and this Addendum represent the entire understanding between the parties on the subject matter and may not be modified except in a writing signed by both parties. Furthermore, except as expressly provided for herein, the terms of the Agreement are in full force and effect.

JOHN GANDOLFO

/s/ John Gandolfo
Signature

EYENOVIA, INC.

By: /s/ Tsontcho Ianchulev
Name: Tsontcho Ianchulev
Title: Chief Executive Officer

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

**Exhibit 10.25**

March 10, 2022

Michael M. Rowe

*Re: Addendum to Executive Employment Agreement*

Dear Mr. Rowe:

The following Addendum represents a modification to the Executive Employment Agreement dated February 15, 2019 (the "Agreement") between Eyenovia, Inc., a Delaware corporation (the "Company"), and Michael M. Rowe (the "Executive") for the express purpose of modifying the terms contained in the Agreement between the parties with respect to the matters below. To the extent that there is an inconsistency between the terms of this Addendum and the terms of the Agreement, the terms of this Addendum shall control. The Agreement is hereby modified, amended or superseded to the extent indicated:

Section 6(a) of the Agreement is hereby superseded by the following:

SEVERANCE. If Executive's employment is terminated by the Company without "Cause" (as such term is defined in the Plan) or Executive suffers an Involuntary Termination (as defined below), provided such termination is a "separation from service" within the meaning of Treasury Regulation § 1.409A-1(h), and provided further that Executive has signed a full general release of all claims in a form reasonably satisfactory to the Company within thirty (30) days of such termination (or such greater time period as required by applicable law for consideration of an employee waiver), Executive will be entitled to receive (i) severance in a total amount equal to twelve (12) months of his then-current Base Salary, less applicable withholdings (the "Severance") and (ii) if Executive properly and timely elects to continue group health insurance benefits under COBRA, reimbursement for his and his spouse and dependents' applicable COBRA premiums for a period of twelve (12) months or until Executive becomes eligible for comparable insurance benefits from another employer, whichever is earlier. The Severance will be paid over a twelve (12) month period in equal installments on the Company's regular payroll schedule beginning on the first pay period following the date the general release of claims is no longer subject to revocation under applicable law.

The Agreement and this Addendum represent the entire understanding between the parties on the subject matter and may not be modified except in a writing signed by both parties. Furthermore, except as expressly provided for herein, the terms of the Agreement are in full force and effect.

MICHAEL M. ROWE

/s/ Michael M. Rowe
Signature

EYENOVIA, INC.

By: /s/ Tsontcho Ianchulev
Name: Tsontcho Ianchulev
Title: Chief Executive Officer

By: /s/ John Gandolfo
Name: John Gandolfo
Title: Chief Financial 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 Forms S-3 (File No. 333-229365, File No. 333-237790 and File No. 333-261638) and Forms S-8 (File No. 333-227049, File No. 333-233278, File No. 333-233280, File No. 333-246288 and File No. 333-261035) of our report dated March 30, 2022, 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, 2021 and 2020 and for each of the two years in the period ended December 31, 2021, which report is included in this Annual Report on Form 10-K of Eyenovia, Inc. for the year ended December 31, 2021.

/s/ Marcum LLP

Marcum LLP
New York, NY
March 30, 2022

**Exhibit 31.1**

**CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER**
**PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Tsontcho Ianchulev, certify that:

1. I have reviewed this annual report on Form 10-K of Eyenovia, Inc. for the year ended December 31, 2021;

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 30, 2022

/s/ Tsontcho Ianchulev
Name: Tsontcho Ianchulev
Title Chief Executive Officer
(Principal Executive Officer)

**Exhibit 31.2**

**CERTIFICATION OF THE PRINCIPAL FINANCIAL 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, 2021;

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 30, 2022

/s/ John Gandolfo
Name: John Gandolfo
Title Chief Financial Officer
(Principal Financial Officer)

**Exhibit 32.1**

**CERTIFICATION OF THE PRINCIPAL EXECUTIVE OFFICER**
**PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the annual report of Eyenovia, Inc. (the "Company") on Form 10-K for the year ended December 31, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Tsontcho Ianchulev, 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 30, 2022

/s/ Tsontcho Ianchulev
Name: Tsontcho Ianchulev
Title Chief Executive Officer
(Principal Executive Officer)

**Exhibit 32.2**

**CERTIFICATION OF THE PRINCIPAL FINANCIAL 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, 2021, 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 30, 2022

/s/ John Gandolfo
Name: John Gandolfo
Title Chief Financial Officer
(Principal Financial Officer)