Risk Factors Comparison 2025-04-15 to 2024-03-18 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

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 **to remain a going concern, which may not be available on acceptable terms, or at all. ● Our ongoing exploration of alternative strategic paths may not result** in **entering into or completing transactions when necessary, and the process of reviewing alternative strategic paths or their conclusion could adversely affect our stock price. ● Delisting of our common stock from Nasdaq could prevent us from maintaining an active, liquid and** ~~order~~ **orderly trading market for our common stock and may materially and adversely impact our ability** to **consummate certain strategic transactions. ● We have entered into a loan modification agreement with Avenue and, based on our lack of financial liquidity, we cannot guarantee that we will be able to comply with the terms of this agreement, or** continue **obtaining forbearance if needed** ~~developing our product candidates and to manufacture and commercialize them and Mydcombi and clobetasol propionate ophthalmic suspension 0. 05 % (" clobetasol propionate "), currently our only FDA- approved commercial products~~ . ● We have incurred operating losses since our inception. We expect to continue to incur losses for the foreseeable future and might never achieve or maintain profitability. ~~● Our relatively short operating history may make it difficult for investors to evaluate the success of our business to date and to assess our future viability.~~ Risks Related to ~~Development~~ **the Proposed Combination between Eyenovia** and ~~Commercialization~~ **Betaliq ● The proposed business combination may not be consummated on the terms described in the non- binding Letter of Intent (as defined herein) or at all. ● Failure to enter into a definitive business combination agreement or consummate the proposed business combination could negatively affect Eyenovia' s business, future business and financial results. ● Eyenovia and Betaliq, Inc. (" Betaliq ") will be subject to various uncertainties while the proposed business combination is pending that could adversely affect the anticipated benefits of the business combination. ● Eyenovia expects to incur substantial transaction costs in connection with the proposed business combination. Risks Related to Regulatory Approval** of Our Products ~~and Product Candidates ● Our ability to achieve profitability is highly dependent on the commercial success of Mydcombi and clobetasol propionate, and to the extent Mydcombi and / or clobetasol propionate is not successful, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline. ● We are dependent on our ability to successfully commercialize our products and our and our licensees' ability to develop, obtain marketing approval for and successfully commercialize our future product candidates. ● Delays in the commencement or completion of clinical testing of product candidates we are developing or may develop in the future may occur and could result in significantly increased costs and longer timelines and could impact our ability to ever become profitable. ● Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval and limit the commercial profile of an approved label, and such side effects or other properties could result in significant negative consequences following any marketing approval of any of our product candidates. ● We might not be able to develop any additional marketable products utilizing our technology and we might not be able to identify and successfully implement an alternative product development strategy. ● If the market opportunities for our products and product candidates are smaller than we believe they are, our product revenues may be adversely affected and our business may suffer. ● The commercial success of our products and product candidates will depend in large part on the degree of market acceptance among ophthalmologists and optometrists, patients, patient advocacy groups, third- party payors and the medical community. Risks Related to Regulatory Approval of Our Product Candidates~~ and Other Legal Compliance Matters ● **We** ~~The regulatory approval processes of the U. S. Food and Drug Administration, or FDA, and comparable foreign authorities~~ are ~~lengthy, time- consuming and inherently unpredictable. If we are not able to obtain required regulatory approval for any of our current or future product candidates, our business may be materially and adversely affected. ● If we receive regulatory approval for any of our current or future product candidates, we will be~~ subject to ongoing regulatory obligations and continued regulatory review **of our products** , which may result in significant additional expense. Additionally, our ~~product~~ **products** ~~candidates, if approved,~~ could be subject to post- market study requirements, marketing and labeling restrictions, and even recall or market withdrawal if unanticipated safety issues are discovered ~~following approval~~ . In addition, we may be subject to penalties or other enforcement action if we fail to comply with regulatory requirements. Risks Related to Our Business Operations and Managing Growth ● We are highly dependent on the services of our senior management team, including our Chief Executive Officer, and if we are not able to retain these members of our management team or recruit and retain additional management, clinical, scientific and sales personnel, our business will be harmed. ● We have limited corporate infrastructure ~~and may experience difficulties in managing growth~~ . Risks Related to Our Dependence on Third Parties ● We ~~rely on third parties to conduct, supervise, and monitor our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects. ● We~~ may encounter delays in the manufacturing of the second generation Optejet device, including as a result of our reliance on third parties for manufacturing activities, and this may cause delays in the commercialization of our products ~~and our product candidatess~~ . Any such delays would increase the risk that we will not have sufficient quantities of our ~~product~~ **products** ~~candidates~~ or such quantities at an acceptable cost, which could delay, prevent or impair our ~~development and~~ commercialization efforts. ● If we, our service providers or our third- party manufacturers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs

that could harm our business. Risks Related to Our Intellectual Property and Potential Litigation ● Our success depends on our ability to protect our intellectual property and proprietary technology. ● Our patents covering our proprietary technology may be subject to challenge, narrowing, circumvention and invalidation by third parties ~~. ● We cannot be sure that we were the first to make the technologies claimed in our patents or patent applications or that we were the first to file for patent protection. 3 ● The patent application process is subject to numerous risks and there can be no assurance that we will be successful in obtaining patents for which we have applied. ● Obtaining and maintaining patent protection of our technologies depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements~~ . ● We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful. ● If we fail to comply with our obligations under our existing and any future intellectual property licenses with third parties, we could lose license rights that are important to our business. Risks Related to Ownership of Our Common Stock ● A significant portion of our total outstanding shares may be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is performing well. ● The price of our common stock has been, and may continue to be, volatile and may fluctuate substantially, which could result in substantial losses for purchasers of our common stock. ● We have broad discretion in the use of our cash, including the net proceeds from our financings, and might not use them effectively. **3** ~~4Item~~ **Item** 1. Business. Corporate InformationWe 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~~ **23461 South Pointe Drive** , Suite ~~2400~~ **390** , ~~New York~~ **Laguna Hills** , ~~NY 10017~~ **CA 92653** , and our phone number is (833) 393- 6684. Our website is www. eyenovia. com. Information contained on, or that can be accessed through, our website is not incorporated by reference into this report, and you should not consider information on our website to be part of this report. OverviewWe are an ophthalmic technology company ~~commercializing Mydcombi ™ (tropicamide and phenylephrine HCL ophthalmic spray) for inducing mydriasis for routine diagnostic procedures and in conditions where short term pupil dilation is desired, preparing for the commercialization of clobetasol propionate ophthalmic suspension 0. 05 % (" clobetasol propionate "), for the treatment of post- operative inflammation and pain following ocular surgery, and~~ developing ~~the~~ **our proprietary** Optejet ® ~~delivery system both for use~~ **topical ophthalmic medication dispensing platform. In November 2024, we received a negative clinical trial result** in ~~combination with~~ **the development of** our ~~own~~ **development- stage** drug- device ~~therapeutic programs~~ **combination product, MicroPine. As a result, we restructured our company to minimize expenses and engaged** ~~and~~ **an** ~~for~~ **investment bank to explore strategic options in order to maximize shareholder value. We have paused the national sales roll-** out ~~- licensing for use in combination with therapeutics for~~ **of our products clobetasol propionate and Mydcombi ® until** additional **funding** ~~indications. Our aim~~ is ~~to improve~~ **obtained. At** the ~~delivery of topical ophthalmic medication through the ergonomic design of~~ **same time, we accelerated our development efforts relating to** the Optejet **in order** ~~which facilitates ease- of- use and delivery of a more physiologically appropriate medication volume, with the goal~~ to **potentially increase the value of that asset in any strategic transaction or capital raising activities** ~~reduce side effects and improve tolerability, and introduce digital health technology to improve therapy compliance and ultimately medical outcomes~~ . The ergonomic and functional design of the Optejet allows for horizontal drug delivery and eliminates the need to tilt the head back or the manual dexterity to squeeze a bottle to administer medications. Drug is delivered in a microscopic array of droplets ~~faster than~~ **that is both comfortable and matches** the ~~blink reflex to help ensure instillation success~~ **amount of fluid that the front of the eye can hold** . The precise delivery of a low- volume columnar spray by the Optejet device ~~minimizes~~ **helps ensure instillation success while minimizing** contamination risk with a non- protruding nozzle and self- closing shutter. In clinical trials, the Optejet has demonstrated that its targeted delivery achieves a high rate of successful administration, with 98 % of sprays being accurately delivered upon first attempt compared to the established rate reported with traditional eye drops of ~~--~~ **approximately** 50 %. A more physiologically appropriate volume of medication in the range of seven to ~~nine~~ **ten** microliters is delivered by the Optejet, which is approximately one- fifth of the 35 to 50 microliter dose typically delivered in a single eye drop. Lower volume of medication exposes the ocular surface to less active ~~ingredient~~ **ingredients** and preservatives, potentially reducing ocular stress and surface damage and improving tolerability. The lower volume also minimizes the potential for drug to enter systemic circulation, with the goal of avoiding some common side effects that are related to overdosing of the eye. We are developing versions of the Optejet with on- board digital technology that records the date and time of each use. These data may be used to provide reminders via Bluetooth to smart devices and to allow healthcare ~~practioners~~ **practitioners** to monitor usage. This information can then be used by practitioners and health care systems to measure treatment compliance and improve medical decision making. In this way, the Optejet could serve as an extension of the physician' s office by providing information that is not currently possible to collect except through the use of diaries. **MicroLine is our investigational pharmacologic treatment for presbyopia, a non- preventable, age- related hardening of the lens, which causes the gradual loss of the eye' s ability to focus on near objects and impairs near visual acuity. We have completed two Phase III studies using our Optejet device. In these studies, patients reported high satisfaction with using the device, and a strong preference over using an eye dropper bottle. Since completing these studies, the market opportunity has markedly deteriorated, and we have chosen to put this program on hold and reallocate our resources towards larger opportunities. When and if the market improves, we have kept open the option to continue development of MicroLine, which would include a meeting with the U. S. Food and Drug Administration (the " FDA ") to review our clinical data to date.** Our **first product using the Optejet technology, Mydcombi ®, is the only FDA- approved fixed combination of the two leading mydriatic agents, tropicamide and phenylephrine, in the United States. As an ophthalmic spray delivered with Optejet technology, Mydcombi may present a number of benefits for ophthalmic surgical centers, optometric and ophthalmic offices and patients. Those**

benefits may include improved cost- effectiveness in centers that employ single- use bottles for mydriasis, more efficient use of office time and resources, and an overall improved doctor- patient experience. The first commercial sale of Mydcombi occurred on August 3, 2023 as part of a targeted launch, and we expanded our launch with the hiring and onboarding of ten sales representatives through December 31, 2024. On July 24, 2024, we received written comments 4 from the FDA providing direction for the design of a clinical bridging study to transition Mydcombi into our new Gen- 2 Optejet device, which has a significantly lower cost to manufacture than the currently approved product. On August 10, 2020, we entered into a license agreement with Arctic Vision (as amended on September 14, 2021, the " Arctic Vision License Agreement ") pursuant to which Arctic Vision may develop and commercialize MicroPine (Eyenovia' s proprietary drug- device ~~product line includes~~ **combination of low- dose atropine and the Optejet platform), MicroLine and** Mydcombi **in Greater China** (~~tropicamide~~ **mainland China, Hong Kong, Macau** and **Taiwan** ~~phenylephrine HCL ophthalmic spray~~) **and South Korea. Under the terms of the Arctic Vision License Agreement** , ~~clobetasol propionate~~ **as amended** , **we received** ~~and~~ - **an upfront payment** ~~therapeutic programs MicroPine (atropine ophthalmic spray) and MicroLine (pilocarpine ophthalmic spray). MicroPine is our first- in- class topical therapy for the treatment~~ of **$ 4** ~~progressive myopia, a disease associated with pathologic axial elongation of the eye and sclero- retinal stretching~~ . ~~In the United States, myopia is estimated to affect approximately~~ 25 million **before any payments** ~~children, with up~~ to **Senju Pharmaceutical Co** ~~five million considered to be at high risk for progressive myopia~~ . ~~In February 2019~~ , **Ltd.** ~~the FDA accepted our Investigational New Drug application~~ (" ~~IND~~ **Senju** ") ~~to initiate the CHAPERONE study to reduce the progression of myopia in children. The first patient was enrolled in the CHAPERONE study in June 2019~~ . On October 9, 2020, we entered into a license agreement (the " Bausch License Agreement ") with Bausch Lomb (" B L "), pursuant to which B L had the rights to develop and commercialize MicroPine in the United States and Canada. Under the terms of the Bausch License Agreement, we received an upfront payment of $ 10. 0 million and we were eligible to receive up to a total of $ 35. 0 million in additional payments, based on the achievement of certain regulatory and launch- based milestones. B L also agreed to pay royalties to Eyenovia on a tiered basis (ranging from mid- single digit to mid- teen percentages) on gross profits from sales of MicroPine ~~5in~~ - **in** the United States and Canada, subject to certain adjustments. Under the terms of the Bausch License Agreement, B L assumed sponsorship of the IND as well as ownership and the costs related to the ongoing CHAPERONE study **, which was a Phase III efficacy and safety trial of MicroPine** . On January 12, 2024, we entered into a subsequent agreement with B L to repatriate our rights to MicroPine and take control of the CHAPERONE study. In this agreement, we agreed to pay B L $ 2 million in cash and an additional $ 3 million in common stock upon successful transfer of the regulatory documents and study elements to Eyenovia. We also agreed to pay B L a 2 % royalty on net sales once MicroPine is commercialized in the United States, assuming receipt of regulatory approvals. We ~~believe~~ **believed** that this ~~new~~ **revised** arrangement ~~is~~ **was** in our and our shareholders' best interests, as it ~~may~~ **could have** substantially ~~increase~~ **increased** the value of the asset ~~significantly~~ through potential improvements in the conduct of the study, including a planned interim analysis of the data in late 2024. **On September 26, 2024, we announced the U. S. launch and commercial availability of clobetasol propionate ophthalmic suspension 0. 05 %. On November 15, 2024, we announced the outcome of an independent review of the clinical results of the three- year efficacy and safety data from the MicroPine Phase III CHAPERONE study conducted by a Data Monitoring Committee (" DMC "). The DMC, made up of independent ophthalmologists and optometrists who specialize in pediatric myopia as well as a statistician, reviewed the safety and efficacy data from all evaluable patients. After the completion of three- year therapy for myopia with MicroPine, statistical superiority was not observed and was deemed unlikely to occur in at least one of the active dose arms compared with placebo, which was the primary efficacy endpoint of the trial. There were no safety issues or serious adverse events identified. As a result of this finding, we closed out the CHAPERONE study and put the project on hold in December 2024. In light of the results from the CHAPERONE study, the Company is considering a variety of steps to maximize value to all stakeholders, to reduce expenses and to evaluate its strategic options, which may include a business combination, reverse merger, asset sales or a combination of those alternatives. Further information will be made available once the evaluation of strategic options has been completed. The Company implemented a reduction in force affecting approximately 75 % of its workforce. The estimated total cost of severance- related expenses relating to this reduction in force is $ 0. 3 million. The remaining staff will be focused on Optejet ® Gen- 2 development, our dry eye collaborations and clobetasol propionate commercialization.** We ~~have also~~ successfully expanded our manufacturing capabilities through a partnership with Coastline International, Inc. located in Tijuana, Mexico, as well as the construction of our new manufacturing facility in Reno, Nevada and the construction of our own fill and finish facility in Redwood City, California. **The** ~~We have received~~ FDA ~~clearance for using~~ **approved the use of** both Coastline International and our Redwood City facility for the production of Mydcombi cartridges, and **the use of** ~~FDA clearance for using~~ our Reno facility for the production of technical elements such as the base unit for the Optejet device. **As part** ~~MicroLine is our investigational pharmacologic treatment for presbyopia, a non- preventable, age- related hardening~~ of the **Company** ~~lens, which causes the gradual loss of the eye~~ ' s **steps to maximize value to all stakeholders, to reduce expenses and to evaluate its strategic options, we made the decision to phase out the production and sale of Mydcombi in the GEN- 1 device. As a result, we have phased out the manufacturing line at Coastline International, Inc. located in Tijuana, Mexico, and are also modifying the use of our manufacturing** ~~ability~~ **facility in Reno, Nevada and our fill and finish facility in Redwood City, California** to focus on ~~near objects and impairs near visual acuity. There are two FDA- approved treatments for presbyopia which use pilocarpine, the same drug used in our investigational product. We have completed two Phase III studies using our~~ Optejet ® ~~device. In these studies, patients reported high satisfaction with using the device, and a strong preference over using an eye dropper bottle. We released positive top- line results from VISION- 2 in the fourth quarter of 2022. We are now planning to meet with the FDA in mid- 2024 to discuss a transition of the product to our new~~ Gen- 2 **development** ~~Optejet device~~ , ~~which has a significantly lower cost to manufacture than the first generation device. Mydcombi is~~ our **dry** ~~fixed~~

~~combination formulation of tropicamide- phenylephrine for inducing mydriasis for diagnostic procedures and in conditions where short term pupil dilation is desired. Mydcombi is a novel approach for the over 106 million office- based comprehensive and diabetic~~ eye **collaborations** ~~exams and 7 million ocular surgeries performed every year in the United States. As the only FDA- approved fixed combination of the two leading mydriatic agents in the United States and as an~~ **and clobetasol propionate** ~~ophthalmic spray, Mydcombi may present a number of benefits for ophthalmic surgical centers, optometric and ophthalmic offices and patients. Those benefits may include improved cost- effectiveness in centers that employ single- use bottles for mydriasis, more efficient use of office time and resources, and an overall improved doctor- patient experience. We are currently commercializing~~ **commercialization . In addition** ~~the product starting with a targeted launch and continuing~~ to ~~expand during 2024, when we expect~~ our **own development programs,** ~~ten sales representatives and internal manufacturing capabilities to come~~ on ~~- line. On~~ August ~~10~~ **15** , ~~2020~~ **2023** , we entered into a license agreement with ~~Aretic Vision (as amended on September 14, 2021, the " Aretic Vision License Agreement ") pursuant to which Aretic 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 Aretic Vision License Agreement, as amended, 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 $ 37. 7 million in additional payments, based on various development and regulatory milestones, including the initiation of clinical research and approvals in Greater China and South Korea, and development costs. Aretic Vision also will purchase its supply of MicroPine, MicroLine and Mydcombi from Eyenovia or, for such products not supplied by Eyenovia, pay a mid- single digit percentage royalty on net sales of such products, subject to certain adjustments. We will pay between 30 and 40 percent of such payments, royalties, or net proceeds of such supply to Senju pursuant to an exclusive license agreement with Senju dated March 8, 2015, as amended (the " Senju License Agreement "). In addition to our own development programs, on August 15, 2023, we entered into a license agreement (the " License ") with~~ Formosa Pharmaceuticals **,** Inc. (" Formosa "), whereby we acquired the exclusive U. S. rights to commercialize any product related to a novel formulation of clobetasol propionate **ophthalmic suspension 0. 05 % (the " Formosa Licensed Product ")** , which was approved by the ~~U. S. Food and Drug Administration (" FDA ")~~ **, for post- operative inflammation and pain after ocular surgery,** on March 4, 2024. **The** ~~On March 13, 2024, the NDA for the product was transferred from~~ Formosa ~~to Eyenovia. The~~ License will remain in effect for ten years from the date of the first commercial sale of ~~clobetasol propionate~~ **a Formosa Licensed Product** , unless earlier terminated. **5** We paid Formosa an upfront payment in an aggregate amount of $ 2 **. 0 million** ~~, 000, 000~~ which consisted of (a) cash in the amount of $ 1 **. 0 million** ~~, 000, 000~~ and (b) 487, 805 shares of common stock valued **pursuant to the Formosa License Agreement** at $ 1 **. 0 million** ~~, 000, 000~~ . We also capitalized $ 122, 945 of transaction costs in connection with the **Formosa** License. In addition, we ~~must~~ **agreed to** pay Formosa up to $ 4 **. 0** million upon the achievement of certain development milestones and up to $ 80 million upon the achievement of certain sales milestones. ~~6We are~~ **The trigger for the initial $ 2. 0 million development milestone payment was FDA approval of the Formosa Licensed Product and the effective date of the acceptance by the Company of the transfer and assignment of the FDA approval, which occurred on March 14, 2024. Based on the achievement of this milestone, we paid Formosa (a) cash** in ~~active discussions~~ **the amount of $ 1. 0 million on April 26, 2024 and (b) 613, 496 shares of common stock (calculated pursuant to the Formosa License Agreement at $ 1. 0 million using a five- day volume- weighted average price on March 14, 2024, but valued at $ 0. 4 million on the April 29, 2024 settlement date). The remaining $ 2. 0 million development milestone (to be fully paid in cash) was earned and accrued upon FDA approval, but payment will be triggered on the earlier of twelve months after FDA approval of the Formosa Licensed Product or six months following the first commercial sale of the Formosa Licensed Product. On August 7, 2024, we entered into a non- binding collaboration agreement** with ~~manufacturers of existing and late~~ **Formosa under which the companies intend to work to develop EYEN** - **530** ~~stage ophthalmic medications to explore whether development with the Optejet technology can solve unmet medical and business needs. Some of those business needs could include extension of exclusivity under the Optejet patents~~ , ~~improvement in~~ a ~~drug~~ **combination of Formosa** ' s ~~tolerability profile,~~ **clobetasol propionate ophthalmic solution with** ~~or~~ **our Optejet dispensing technology, as a** potential ~~improvement in~~ treatment **for acute dry eye flare- ups. On November 22, 2024, we entered into the First Amendment (the " First Amendment ") to the Supplement to that certain Loan and Security Agreement, dated November 22, 2022 (the " Loan and Security Agreement ") with Avenue Capital Management II, L. P., as administrative agent and collateral agent, Avenue Venture Opportunities Fund, L. P., as a lender and Avenue Venture Opportunities Fund II, L. P., as a lender (together, " Avenue "). Pursuant to the First Amendment, Avenue agreed to defer principal and interest payments on amounts outstanding under the Loan and Security Agreement until the end of February 2025. On February 21, 2025, we entered into the Second Amendment (the " Second Amendment ") to the Supplement to the Loan and Security Agreement with Avenue. Pursuant to the Second Amendment, Avenue agreed to defer principal and interest payments on amounts outstanding until the end of September 2025. Deferred interest will accrue on the outstanding principal amount at the interest rate (as defined in the Second Amendment). On December 12, 2024, we announced the engagement of Chardan Capital Markets, LLC (" Chardan "), an investment bank, as the Company' s financial advisor in connection with its evaluation of strategic alternatives. With assistance from Chardan, the Company will continue to assess a full range of strategic alternatives, including but not limited to, a business combination, sale of the Company, reverse merger, asset sale, or a combination of alternatives, while also carefully managing its expenses. As part of restructuring to minimize expenses during this process, the Company temporarily halted sales and promotion activities and focused its development efforts on completing the verification and validation studies required for regulatory approval of the Optejet UFD. This device is designed for users to fill with preserved artificial tears or contact lens rewetting solutions at home, providing greater flexibility while leveraging Optejet' s advanced delivery system. As of March 2025, Eyenovia is progressing with its development of the Optejet UFD, aiming for a 510K submission in the United States in the fourth quarter of 2025. On**

July 26, 2024, we received notice from the staff (the " Staff ") of The Nasdaq Stock Market LLC (" Nasdaq ") providing notification that the Company had regained compliance **with the $ 1** . **00 minimum bid price requirement for continued listing on** The **Nasdaq Capital Market under Listing Rule 5550 (a) (2). Previously, Nasdaq had notified us on July 2, 2024 that, for the preceding 30 consecutive business days, the closing bid price of our common stock had been below the minimum requirement of $ 1. 00 per share. The notification letter stated that we would be provided 180 calendar days to regain compliance. In order to regain compliance, the closing bid price of our common stock had to be at least $ 1. 00 for a minimum of 10 consecutive business days at any time before December 30, 2024. Subsequently, the Staff determined that, from July 12 to July 25, 2024, the closing bid price of our common stock had been at $ 1. 00 per share or greater. Accordingly, the Company had regained compliance with Listing Rule 5550 (a) (2). On February 25, 2025, we received notice from the Staff of Nasdaq providing notification that the Company had regained compliance with the $ 1. 00 minimum bid price requirement for continued listing on The Nasdaq Capital Market under Listing Rule 5550 (a) (2). Previously, Nasdaq had notified us on September 18, 2024 that, for the preceding 30 consecutive business days, the closing bid price of our common stock had been below the minimum requirement of $ 1. 00 per share. The notification letter stated that we would be provided 180 calendar days to regain compliance. In order to regain compliance, the closing bid price of our common stock had to be at least $ 1. 00 for a minimum of 10 consecutive business days at any time before March 17, 2025. On January 31, 2025, the Company effected a reverse stock split of its common stock at a ratio of 1- for- 80 (the " Reverse Split "). Upon the effectiveness of the Reverse Split, every 80 issued shares of common stock were reclassified and combined into one share of common stock and the corresponding price per share increased by a multiple of 80. Subsequently, the Staff determined that, from February 3 to February 14, 2025, the closing bid price of our common stock had been at $ 1. 00 per share or greater. Accordingly, the Company had regained compliance with Listing Rule 5550 (a) (2). 6 Recent DevelopmentOn March 18, 2025 we entered into a non- binding letter of intent (the " Letter of Intent ") with Betaliq, a Delaware corporation, relating to a proposed business combination between Eyenovia and Betaliq. Betaliq is a clinical stage pharmaceutical company with a therapeutic focus on Glaucoma, founded in 2018 through a collaboration with Novaliq GmbH. The parties currently contemplate a reverse merger structure, pursuant to which (i) a newly- formed, wholly- owned subsidiary of Eyenovia would merge with and into Betaliq, with Betaliq as the surviving corporation and a wholly- owned subsidiary of Eyenovia, and (ii) Betaliq would then immediately merge with and into a second newly- formed wholly- owned subsidiary of Eyenovia (the " Second Merger Sub "), with the Second Merger Sub as the surviving corporation. In connection with the closing of the transaction, Eyenovia expects to change its name to " Betaliq, Inc. " or such other name as determined by Betaliq and change its trading symbol as determined by Betaliq. As contemplated by the Letter of Intent, Betaliq stockholders would receive (a) shares of Eyenovia common stock (" Eyenovia Common Stock ") and (b) securities convertible into Eyenovia Common Stock in exchange for their shares of Betaliq capital stock (" Betaliq Capital Stock ") based on the Exchange Ratio (defined below). Outstanding equity awards, convertible notes, warrants, and any other equity interests or instruments convertible into Betaliq Capital Stock (" Betaliq Stock Rights ") would be assumed by Eyenovia and become the equity awards, convertible notes, warrants, and any other equity interests or instruments convertible into equity interests of Eyenovia, as applicable, based on the Exchange Ratio in a manner mutually agreeable to Betaliq and Eyenovia. As contemplated by the Letter of Intent, the conversion of the Betaliq Capital Stock and Betaliq Stock Rights would be effected pursuant to an exchange ratio (the " Exchange Ratio ") intended to result in the** following ~~summarizes our product pipeline and anticipated milestones~~ **approximate aggregate post- closing percentage ownership** : ~~Product or ProductCandidate Indication Next Expected MilestonesMydcombi ™ Pharmaceutical Mydriasis~~ (**i** ~~Pupil Dilation~~) **the equity holders of Betaliq immediately prior to the closing** ~~Approved; Commercial Launch UnderwayClobetasol PropionatePost Ocular Surgery Pain and InflammationApproved; Commercial Launch PendingMicroLineImprovement in Near Vision~~ (~~Presbyopia~~ **including all Betaliq Stock Rights**) ~~Pre- NDA Meeting Mid- 2024MicroPinePediatric Myopia Progression~~ **would own approximately 83. 7 % of the equity of the combined company on a fully diluted basis, and** (**ii** ~~Near- Sightedness~~) ~~Phase III CHAPERONE Ongoing; Planned Phase III Interim Analysis Q4 2024Our~~ **the equity holders of Eyenovia immediately prior to the closing (including outstanding equity awards, convertible notes, warrants, and any other securities or instruments convertible into or exercisable for equity interests of Eyenovia) would own approximately 16. 3 % of the equity of the combined company on a fully diluted basis. These ownership percentages assume a valuation of approximately $ 77 million for Betaliq and approximately $ 15 million for Eyenovia, Eyenovia " net cash " (which will include, among other things, unrestricted current assets in the form of cash and cash equivalents as of the closing minus current liabilities and all expenses related to the proposed transaction as of the closing) of zero at closing, and the inclusion of Optejet and related Eyenovia assets, and are subject to adjustment as described in the Letter of Intent. Following the closing of the business combination, the combined company' s board of directors will be comprised of members to be mutually agreed upon by the parties. Assuming signing and closing of the definitive agreement occurs, stockholder approval of the issuance of Eyenovia securities in excess of limits imposed by Nasdaq listing rules to the former Betaliq stockholders will be sought at a meeting to take place following the closing. The parties intend to negotiate a definitive business combination agreement consistent with the provisions of the Letter of Intent as well as other terms and conditions typical for transactions of this nature. During the binding exclusivity period set forth in the Letter of Intent, which ends on May 16, 2025 but is subject to extension, the parties have agreed not to solicit or encourage submission of, or participate in discussions or enter into any agreement regarding any other acquisition proposal. Our** ~~StrategyOur~~ **StrategyWe are currently exploring strategic business options intended to maximize shareholder value including, if possible, continued commercialization of Mydcombi and clobetasol propionate and completing the development of our Optejet device. Our** goal is to become a leading developer and ~~provider~~ **licensor** of ~~advanced ophthalmic therapies based upon our microdose array~~

~~print (MAP) platform technology~~ **the Optejet in multiple formats; beginning with the UFD, then adding device- drug combinations** and **a** digital health platform for ~~interactive~~ **improved** patient care **outcomes** . These unique products would be commercialized **internally** ~~by us~~ and / or ~~our~~ **with licensees and development** partners globally. The key elements of our strategy to achieve this goal are: **Obtain clearance from the U. S. FDA on the Optejet ® UFD through the 510K pathway. We are focused on submitting the Optejet for use with artificial tears and contact lens rewetting solutions as a device to the FDA. Successful clearance from the FDA would then** ~~Establish~~ **establish the existing device for later drug- device submissions through the 505 (b) (2) registration pathway, which may reduce development risk compared to new molecular entity programs by working with known compounds with well- established safety and efficacy profiles. Through partnerships and licensings agreements, establish** a portfolio of first- in- class piezo- print micro- therapeutic products for multiple eye treatments through the 505 (b) (2) pathway with the FDA. We are focused on integrating our next-generation technology with therapeutic compounds already well established in the topical treatment of ophthalmic indications. We believe that the 505 (b) (2) registration pathway, which **may** ~~reduces~~ **reduce** development risk compared to new molecular entity programs by working with **7** known compounds with well- established safety and efficacy profiles, will be available for our development pipeline. We believe ~~our~~ **a** pipeline of patented micro- therapeutic product candidates ~~is~~ **would be** highly differentiated by our improved tolerability and enhanced compliance profile and that our late- stage development programs could lead to additional NDA submissions in novel indications where the products can have unique dosing and therapeutic profiles. We believe that this could lead to favorable pricing and a reduced risk of generic competition. Improve clinical outcomes and patient experiences while providing an improved tolerability profile with our microdose therapeutics. We believe the Optejet will allow for high precision targeted microdosing for multiple eye treatments, while eliminating ophthalmic over-dosing and reducing ocular exposure to toxic preservatives and pharmacologic ingredients compared to conventional eye drop delivery mechanisms. Our clinical trials have demonstrated similar efficacy to eye drops, as well as improved side effect profile and enhanced patient experience with the Optejet as compared to conventional eye drops. Leverage our Optecare ™ technology to introduce and develop patient- specific compliance and treatment adherence enhancement programs. The Optejet' s mobile e-health technology **, Optecare,** is designed to track when a patient administers treatments, allowing physicians to monitor patient compliance more accurately. We believe this could enhance patient compliance and improve compliance monitoring by empowering patients and physicians with access to dynamic, real- time monitoring and compliance data for a more intelligent, informed and personalized therapeutic paradigm. Develop next- generation targeted microdose treatments for other ophthalmic diseases ~~independently or~~ in collaboration with third parties. The Optejet also may be suitable for new molecular entities and applications. Leveraging our existing platform technology, we plan to continue developing, either independently or through strategic relationships with third parties, other product candidates for various eye diseases that can be administered using the Optejet and additional applications for the Optejet. ~~Develop therapeutic solutions for ophthalmic conditions with high unmet needs and no approved therapy. We plan to target chronic ophthalmic conditions with a high unmet medical need. By leveraging our piezo- print microdosing technology, we aim to reach conditions where there are no approved drug therapies. For example, our MicroPine program involves a proprietary formulation of low- dose atropine intended to slow myopia progression in the pediatric population. There are currently no commercially- available medical therapies in the United States to treat this indication. 7Limitations~~ **Limitations** of Conventional Eye TherapiesOur microdosing platform technology aims to address the following issues associated with conventional eye drop- based therapies: Dosing and ease of administrationMultiple third- party studies have confirmed challenges with administering conventional eye drops, which include overdosing, poor compliance, imprecise dosing, variability in drop size, and difficulty with self- administration. One study in patients who were experienced in using eye drops and undergoing treatment for glaucoma for at least six months documented that nine out of ten patients were unable to administer treatment correctly at the end of the six- month study. Patients on average administered almost twice the necessary number of drops with a mean number of drops instilled at 1. 8 (/ ~~1 .~~ 1. 2) and one patient administered up to eight drops at one time. In addition, approximately 75 % of patients risked bottle contamination or potential ocular trauma by having the eye drop container touch their eyes. Another larger study in 139 patients demonstrated that the proportion of patients able to correctly administer their eye drops was only 22 % – 30 %. Similarly, other studies have demonstrated that the vast majority of patients either overdose or do not administer the required therapy to the eye correctly, which may lead to additional side effects or lack of efficacy. Side effects associated with conventional eye drop therapiesTopical eye therapies are administered using traditional eye drop pipette approaches. While average tear volume of the eye is 6 – 8 µL, current eye drop therapies can involve administration of 30 – 50 µL of liquid containing preservatives and pharmaceutical ingredients. Thus, traditional drops can severely overdose the eye, which, depending on the ingredients, can be associated with ocular side effects including hyperemia, or increased blood flow to the eye, redness, discomfort, stinging, blurred vision, burning, itching, excessive tearing, eye pain, iris pigment changes, foreign body sensation, pigment discoloration, periorbital dermatitis and sunken eye. For some topical medications, there also can be cardiovascular side effects such as changes in heart rate and arrhythmia that are caused when medications are absorbed into the circulation system from overdosing both through conjunctiva absorption and when drugs flow into the nose through the naso- lacrimal duct and are absorbed into the systemic circulation or swallowed. For example, phenylephrine can cause cardiovascular adverse reactions including an increase in blood pressure, syncope, myocardial infarction, tachycardia, arrhythmia and subarachnoid hemorrhage. Severe respiratory reactions and cardiac reactions, including death due to bronchospasm in patients with asthma, and rarely death in association with cardiac failure, have been reported following systemic or ophthalmic administration of timolol maleate. **8** ~~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. 8Our~~ **Our** Solution: The **OptejetOptejet Base and CartridgeIn** ~~OptejetGen- 1Gen- 2In~~ UseThe Optejet dispenser delivers doses of approximately 7- 9 µL, directly coating the corneal surface where 80 % of intraocular drug penetration occurs. We believe that microdosing may reduce drug and toxic preservative exposure by more than 75 %, thus reducing ocular irritation, and resulting in potentially gentler treatments without compromising the desired clinical effect. We believe that we are ~~one of~~ the only ~~companies~~ **company** with ~~clinical stage technology for~~ **an FDA- approved product that uses a** targeted **, metered** ~~microdosing~~ **microdosed spray** of ophthalmic ~~investigational~~ **topical** ~~therapies~~ **therapy** ~~having fully completed the Phase III clinical studies needed and made an NDA submission~~. The Optejet is based on **microdose array print, or** MAP **, technology**, which is also used for pixel- sharp high- precision inkjet printing. The technology is optimized for and applied in ophthalmic delivery to achieve microdosing that can be many times more precise than conventional eye droppers. In addition, our smart, electronic system provides the capability to track when patients administer their medications and deliver this information to patients and physicians via Bluetooth connectivity. Thus, physicians can make decisions regarding therapeutic regimens with knowledge of patient compliance. ~~The FDA has determined that our Optejet products are 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: **9** ~~9Dose~~ **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. **10** ~~10Speed~~ **Speed** of delivery: Our piezo- print technology is similar to high- precision ink- jet printing. Unlike a simple aerosolized mechanism, the Optejet is designed with ejection control that creates a fast and targeted micro- jet delivery. Solution is dispensed to the ocular surface in less time than the average involuntary blink reflex from the time the first droplet hits the corneal surface to the completion of dose delivery. Smart electronics: A key feature of the Optejet is the embedded electronic, Bluetooth enabled Optecare system, which we believe is the first intelligent electronic delivery system for ophthalmic therapies. Our electronic functions are designed to enable patients and physicians to track when doses are administered. We believe this technology will improve compliance and chronic disease management by empowering patients and physicians with access to dynamic, real time monitoring and compliance data for a more intelligent and personalized therapeutic paradigm. Recent changes in payment codes may now provide a way for healthcare providers to bill for this important service. Clinical Trial ResultsWe 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. **11** Diurnal IOP Lowering Effect of a Microdose of Latanoprost Delivered by Pipette vs. Piezo- Print Dispenser in a Canine ~~Model11IOP~~ **ModelIOP** Lowering Effect of Micro- Therapeutic Dose of Latanoprost in Canine ModelThe 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. **12** Shown below is mean pupil diameter change from baseline for the 24 eyes studied. The asterisk at t = 75 min indicates EYN ~~is~~ **was observed to be** statistically better than PE 2. 5 % (p = 0. 009). PUPIL DIAMETER, INCREASE FROM BASELINE, ~~MM12This~~ **MMThis** 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 %). 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 TREATMENTPE 10 % EYNAdverse Event Description (Eyedrops) (PE 10 % microdose) Ocular blurriness 1 0Ocular burning / stinging / irritation 4 1Ocular dryness 2 0Subtotal by Treatment Group 7 **113** ~~1The~~ **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 ~~13the~~ -- **the** Optejet. Thirty healthy volunteer subjects (60 eyes) were evaluated for eligibility and consented to study participation. Subsequently, at each of three treatment visits, IOP was measured in the morning. Afterwards, on Treatment Days 1 and 2, a single 8- µL microdose of latanoprost 0. 005 % ophthalmic solution was administered to each eye using the Optejet. On the morning of Treatment Day 3, each subject received 2 × 8- µL Optejet microdoses (administered approximately 5 minutes apart) in one eye and the other eye received a single eye drop of latanoprost 0. 005 % ophthalmic solution. For each treatment day, IOP was measured 1, 7, 12, and 24 hours after receiving medication and a mean diurnal IOP was calculated from the four readings. As shown below, mean IOP after medication administration on Days 1 and 2 was lowered by 25. 0 % and 28. 7 %, respectively. Mean bilateral IOP and percent change in IOP in eyes dosed using the Optejet throughTreatment Day 2 (N = 29 pairs of eyes from 29 evaluable subjects) **14** As shown below, on Day 3, mean IOP was 35. 5 % lower than baseline for eyes receiving microdose latanoprost 0. 005 % using the Optejet, and 35. 0 % lower than baseline for eyes receiving a single drop of latanoprost 0. 005 %. IOP AT DAY 3 (N = 29 EYES OF 29 SUBJECTS PER TREATMENT) No clinically significant changes were noted in slit lamp observations (including hyperemia) for any subjects who received study treatment and no adverse events were reported. Subjects reported no- to- negligible ocular discomfort after medication administration using the Optejet. Investigator- administered medication using the Optejet was evaluated in 60 eyes (1 spray / eye) on Days 1 and 2, and in 30 eyes (2 sprays / eye) on Day 3. Optejet administration was successful on the first attempt in 172 of the 180 cases (96 %). Subject head movement and / or blinking and investigator proficiency with Optejet use resulted in the need for additional administration in the remaining 4 % of cases, the majority of which (6 / 8) occurred on Day 1. Administration success was achieved on the first attempt on all Day 3 cases. There were no reports of unintentional overdosing, tear fluid overflow, or the dispenser nozzle touching the eye. In a separate evaluation, subjects were trained on Optejet self- administration with sterile water and then asked to demonstrate Optejet use in each eye during the afternoon of each treatment day. By the afternoon of Day 3, qualified Eyenovia representatives judged that almost 90 % of subjects were able to demonstrate accurate self- administration using the Optejet. ~~14This~~ -- **This** study demonstrated Optejet medication administration to be easy to perform, safe, and comfortable to study subjects. Additionally, Optejet microdose administration of 0. 005 % latanoprost resulted in mean IOP reduction similar to reported literature for use of latanoprost 0. 005 % ophthalmic solution administered as traditional eye drops. Based on the results of these studies further validating microdose delivery of ophthalmic medication, we initiated Phase III programs in mydriasis in late 2018, progressive myopia in 2019, and presbyopia in 2020. **On May 5, 2023, we received notification from the FDA of the approval of Mydcombi (tropicamide and phenylephrine metered ophthalmic spray) for diagnostic pupil dilation. The approved label for the product was advantageous compared with eye drop formulations, with adverse events being infrequent and mild and the incidence of stinging at less than 1 % in clinical studies.** Our **Products and** Product ~~and Product CandidatesEyenovia~~ - **CandidateEyenovia** currently ~~has~~ **owns or licenses** two FDA- approved products, Mydcombi and clobetasol propionate ~~, and two research programs: MicroLine (for presbyopia) and MicroPine (for progressive myopia)~~ . MydcombiMydcombi is the only FDA- approved fixed combination of the two leading pupil dilation drugs, tropicamide and phenylephrine, delivered with our Optejet technology. The product is indicted to induce mydriasis (pupil dilation) for routine diagnostic procedures and in conditions where short term pupil dilation is desired. There are approximately 106 million estimated office- based comprehensive and diabetic eye exams and seven million ophthalmic surgical dilations performed every year in the United States. The benefits of Mydcombi include effective, reliable dilation with low risk of cross- contamination as compared with eye dropper bottles, ease of use for technicians and doctors, and good tolerability for patients. **15** ~~We believe the market for Mydcombi exceeds $ 250 million in the United States alone.~~ Background of Mydriasis and Market OpportunityThere are an estimated 106 million topical mydriatic applications performed every year as a required part of the comprehensive dilated eye exam and standard retina fundoscopy for diabetic retinopathy screening, macular degeneration evaluation, glaucoma optic disc evaluation and many other back- of- the- eye conditions. There are an additional estimated four million applications for ocular surgery. Most optometrist and ophthalmologist offices maintain bottles of both phenylephrine and tropicamide eyedrops and use the drops in combination. Each bottle is used on multiple patients, which carries a risk of contamination and ocular infection. The bottles are purchased directly from suppliers and are not subject to insurance reimbursement. Our combination therapy allows the purchase of one product for eye dilation. Additionally, the Optejet does not come in direct contact with the eye, thus minimizing the risk of infection. Most dilated eye exams require the sequential administration of two separate topical pharmacologic agents / drops (tropicamide, followed by phenylephrine). All current mydriatic formulations use conventional macrodose drop delivery (30 – 50 µL), which can significantly overdose the ocular surface whose physiologic capacity is only 6 – 8 µL. Studies demonstrate that standard macrodosed pharmacologic dilation is associated with significant ocular discomfort and mild- moderate eye pain. On the standard visual analogue scale for pain, such discomfort can exceed the levels of pain associated with a flu vaccine subcutaneous injection. Additionally, there are systemic safety concerns with mydriatic macrodosing for retinopathy of prematurity retinal screening and pediatric dilated eye exams. Studies comparing microdosed phenylephrine and cyclopentolate to traditional eye drops (30 – 50 µL drop size) in premature babies and in full- term infants have shown equivalent pupil dilation with drop sizes ranging from 5 – 8 µL while reducing systemic levels by more than 50 %. Pharmacologic mydriasis: dilated pupil after ~~application15Efficacy~~ -- **applicationEfficacy** and ~~Safety16The~~ --- **Safety16 The** above diagram represents the pooled data (MIST- 1 and MIST- 2) from the approved labeling for Mydcombi. The graph summarizes pupil diameter over time. Vertical bars show 95 % confidence interval for the mean at each point. Smooth curves are based on 8 degrees of freedom (df) generalized additive model (GAM) smooth through time, adjusting for baseline pupil diameter. Confidence intervals are not adjusted for correlation. Mydcombi (TR- PH) was statistically and clinically superior to its components (TR – tropicamide, PH – phenylephrine) as well as placebo at all timepoints post- dosing. By ~~twenty~~ **20** minutes post- dosing, the mean pupil dilation was above 6mm, more than sufficient for a

thorough clinical examination. All adverse events were transient and mild and occurred in fewer than 2 % of patients . Commercial PlansWe plan to hire a ten- person sales team, managed by two experienced sales directors, to promote Mydcombi directly to institutions and key ophthalmic and optometric offices. We have obtained wholesale licenses nation- wide and will be handling distribution internally to maintain control over the product and help ensure a good experience for this novel technology. Ordering and reordering will be managed on- line at EyenoviaRx. com . Clobetasol Propionate We have licensed this topical ocular steroid from Formosa Pharmaceuticals and will have commercial rights to this product within the United States. The product was approved by the FDA on March 4, 2024. This unique post- ocular surgery steroid is the first product developed using Formosa' s proprietary APNT nanoparticle formulation platform, which reduces an active pharmaceutical ingredient' s particle size with high uniformity and purity, thereby allowing penetration to relevant compartments in the eye, and ultimately enhancing bioavailability. Clobetasol propionate will be the first new steroid in this market in over 15 years, and one of the few that is dosed twice- daily (instead of up to 4 times daily) without the need to taper dosing over a 14 day course of therapy. With 7 million ocular surgeries conducted annually in the United States, we estimate the market opportunity for this product to be over $ 200 million. In clinical studies, clobetasol propionate was very effective, with approximately 90 % of patients experiencing zero pain towards the end of therapy. Adverse events were few and mild, including 1 % of patients experiencing elevated intraocular pressure, which may have been related to the surgery itself. We plan to leverage our Mydcombi sales team to also cover promotion of this new, differentiated eye drop, with an anticipated launch in the second half of 2024. MicroLine MicroLine is our **investigational** proprietary microdosed version of pilocarpine, a well- understood ophthalmic medication that can dose- dependently induce miosis, or a contraction of the pupil. It is a direct acting cholinergic parasympathomimetic agent that stimulates muscarinic acetylcholine receptors present on smooth muscles, including those in the iris and ciliary body. As a result, pilocarpine causes contraction of the iris sphincter muscle, which causes miosis. Reducing pupil size with pilocarpine has been shown to improve near visual acuity in individuals who have presbyopia. In one clinical study, subjects aged 45 – 50 years who bilaterally self- administered both pilocarpine 1 % and diclofenac 0. 1 % eyedrops every six hours during the day for up to five years reported good improvement in near vision without compromising distance vision. Thus, pilocarpine' s miotic effect may be useful in treating the increasingly compromised near vision that parallels the development of presbyopia. Background of Presbyopia and Market OpportunityPresbyopia 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. 17For -- **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 **We believe** MicroLine , we plan **may have the potential** to introduce **be** a pharmaceutical option for improving near vision that can work as a companion to spectacles, for when patients wish not to use their reading glasses. Our market research indicates the highest interest in the product concept among people aged 40 to 55 years who otherwise have normal vision and household income in the top half of the country, representing a potential market of approximately 18 million people. Phase III Clinical Development ProgramsWe **have completed two Phase III studies** are evaluating whether topical ocular microdosing of pilocarpine using the **our** Optejet **device** 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 **study** , VISION- 1, showed that pilocarpine 2 % provided a statistically superior improvement in functional near vision and an acceptable safety profile in presbyopic **17** subjects with baseline distance- corrected near visual acuity better than 20 / 80. Our second Phase III study, VISION- 2 evaluated the safety, tolerability, and efficacy of Optejet- administered microdosing of pilocarpine 2 % as an ophthalmic spray versus placebo. **Since completing** MicroPineA key therapeutic program for Eyenovia is our first- in- class topical treatment for pediatric progressive myopia, a disease reaching epidemic proportions according to the American Academy of Ophthlmology. Background of Progressive Myopia and Market OpportunityMyopia 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. Progressive Myopia with Retinal Atrophy ChangesWhile currently there **these studies** are no FDA- approved therapies for myopia progression , there -- **the** 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 18treatment of progressive myopia in the pediatric population, thus impeding the drug' s clinical utility and adoption for myopia progression. 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. Delivered with the Optejet dispenser, the product is also intended to make use of the Optejet' s Optecare system to assist with compliance and adherence. The potential market opportunity for MicroPine in the United States alone may be $ 1. 2 billion, according to third party analysts. Phase -- **has** III Clinical **markedly deteriorated, and we have chosen to put this program on hold and reallocate our resources towards larger opportunities.**

When and if the market improves, we have kept open the option to continue ~~Development~~ **development** ~~ProgramThe~~ **of MicroLine, which would include a meeting with 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~~ **to review** ~~MicroPine treatment concentrations or~~ **our clinical data to** ~~a placebo control arm. The primary assessment of efficacy is based on reduction in myopia progression after 3 years of medication use. We expect that over half of the intended enrollment of CHAPERONE will have reached the three- year efficacy endpoint in late~~ **date** ~~2024. At that time, we plan to discuss an interim analysis with the FDA to determine if there is a more efficient pathway towards approval for the product~~. Our TechnologyThe 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 ~~19quickly~~ -- **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 MarketingWe are building a sales and distribution organization that will be staged to match with our planned product launches and size of the opportunities. We have hired and plan to deploy ten sales representatives and two national sales directors who will focus on the promotion of Mydcombi as well as clobetasol propionate. We have also built the infrastructure to act as a wholesaler for Mydcombi, and will be partnering with an online pharmacy for the launch of clobetasol propionate. 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 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. Clobetasol propionate is our second product for commercialization. Like Mydcombi, clobetasol will also be " cash- pay, " negating the need for infrastructure focused on managed care reimbursement. Clobetasol will be sold in two ways: (1) prescribed by ocular surgeons to patients through an online pharmacy, and (2) purchased directly from Eyenovia by offices who sell the medication directly to their patients as part of their overall fee. MicroLine, if approved, would again be " cash- pay ". If we decide to pursue approval, and receive approval, for this product, we would expand our sales force 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 fourth expected product for commercialization. MicroPine is planned to be launched as a reimbursed product, similar to glaucoma medications, where formulatory position is obtained through negotiations with payers. We would make use of our planned sales force calling on optometrists, many who have a specialty in treating pediatric progressive myopia~~. ManufacturingFor clinical supply, Eyenovia relies on internal manufacturing capabilities along with third- party contract manufacturing organizations (CMOs) to produce the Optejet ® cartridges and bases. In order to streamline our manufacturing process and reduce costs, Eyenovia has invested in two of its own facilities, one in Redwood City, CA that **is** ~~was recently~~ FDA- approved for Mydcombi cartridge production, and one in Reno, NV that **is** ~~has recently been~~ FDA- approved for ejector and base unit manufacturing. We also use a CMO, Coastline International in Mexico, for production of certain subassemblies as well as a CMO for the production of our drug substances. We are currently developing and manufacturing the second generation of our device, and **on July 24, 2024,** we **received written comments** ~~expect our strategy for moving~~ from the ~~first to~~ **FDA broadly outlining** the ~~second generation~~ **design of a clinical bridging study to transition Mydcombi into our new Gen- 2 Optejet** device ~~to be the subject of an FDA meeting this summer~~. Assuming we come to an agreement with the FDA to demonstrate comparability between the two devices, this should provide a **two- year** path for Eyenovia to introduce the second generation platform ~~to the commercial market in 2026~~. ~~20CompetitionThe~~ -- **CompetitionThe** 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 **18** through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient enrollment for clinical trials, as well as in acquiring products, product candidates or other technologies that we may target to in- license or acquire in pursuit of our updated business plan. For Mydcombi, we are not aware of any micro- therapeutics nor of any existing FDA- approved tropicamide- phenylephrine topical fixed combination products even in standard macrodose. There are competitive macrodose drop formulations of individual therapeutics for mydriasis such as tropicamide and phenylephrine marketed by companies such as Akorn, Alcon and others, as well as pharmacies that compound the combination on an individual basis for physicians. For clobetasol propionate, there are several steroid options in this field, but we are not aware of any product with the combination of dosing, efficacy and safety attributes that our product will have. Additionally, we believe our " value pricing " approach, where patients can expect to pay a fixed amount regardless of their insurance coverage or status, will further differentiate us in this market. ~~For MicroLine, Allergan has launched Vuity, a pilocarpine eye drop for the treatment of presbyopia. Along with Allergan, there are other pharmaceutical companies developing therapies for presbyopia, none of which makes use of microdosing technology or deliver medication as a spray. 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 PropertyOur 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. ~~We are currently engaged in an appeal taken from three inter partes review (" IPR ") proceedings successfully challenging the validity of certain patents owned by Sydnexis, Inc. The Patent Trial and Appeal Board instituted IPR2022- 00384, filed by Eyenovia on December 29, 2021 and challenging claims in U. S. Patent No. 10, 842, 787; and IPR2022- 00414 and IPR2022- 00415, both filed by Eyenovia on January 7, 2022, and challenging claims in U. S. Patent Nos. 10, 940, 145 and 10, 888, 557, respectively. All three IPR proceedings were instituted and then consolidated for trial. On July 13, 2023, the Board determined in a final written decision that all claims across the three challenged Sydnexis patents were unpatentable. Sydnexis subsequently appealed to the U. S. Court of Appeals for the Federal Circuit, and briefing is currently in progress, with a decision anticipated in 2025. 21PatentsAs~~ - **PatentsAs** of December 31, ~~2023~~ **2024** , we owned ~~seventeen~~ **twenty- two** U. S. issued and allowed utility patents or design patents, and ~~ten~~ **nine** pending U. S. patent applications, as well as ~~97~~ **101** issued foreign patents, and ~~26~~ **23** 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. **19** ● 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 ~~22extension --~~ **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. TrademarksOur 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: APERSURETM, EYENOVIA ®, OPTEJET ®, EYELATOVATM, EYETANOTM ~~,~~ **and** MYDCOMBITM. 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 TechnologyIn 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 ApprovalsGovernment 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 **20** 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 RegulationIn 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. ~~23FDA --~~ **FDA** Regulation of Prescription DrugsAn applicant seeking approval to market and distribute a new drug product in the United States must typically undertake the following: ● completion of nonclinical studies, which may include laboratory testing, animal studies and formulation studies in compliance with the FDA' s good laboratory practice, or GLP, regulations; ● submission to the FDA of an IND which must take effect before human clinical trials may begin; ● approval by an institutional review board, or IRB, an independent committee charged with protecting the rights and welfare of human research subjects participating in clinical trials, before each clinical trial site may initiate clinical trial enrollment; ● performance of adequate and well- controlled human clinical trial (s) in accordance with good clinical practice, or GCP, regulations to establish the safety and efficacy of the proposed drug product for each indication; ● preparation and submission to the FDA of an NDA; ● review of the product by an FDA advisory committee, where appropriate or if applicable; ● satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with current good manufacturing practice, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the product' s identity, strength, quality and purity; ● satisfactory completion of FDA audits of selected clinical trial sites to assure compliance with GCP requirements and the integrity of the clinical data; ● payment of user fees, with few exceptions, and securing FDA approval of the NDA; and ● compliance with any post- approval requirements, including Risk Evaluation and Mitigation Strategies, or REMS, and post- approval studies required by the FDA. Preclinical TestingPreclinical, or nonclinical, testing include laboratory evaluation of the purity and stability of the manufactured drug substance or active pharmaceutical ingredient and the formulated drug or drug product, and generally include in vitro and animal studies to assess the toxicity, safety and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. The conduct of preclinical studies

is subject to federal regulations and requirements, including GLP regulations. The Consolidated Appropriations Act for 2023, signed into law on December 29, 2022, (P. L. 117- 328) amended the FDCA and the Public Health Service Act to specify that nonclinical testing for drugs and biologics may, but is not required to, include in vivo animal testing. According to the amended language, a sponsor may fulfill nonclinical testing requirements by completing various in vitro assays (e. g., cell- based assays, organ chips, or **21** microphysiological systems), in silico studies (i. e., computer modeling), other human or nonhuman biology-based tests (e. g., bioprinting), or in vivo animal tests. The results of the nonclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. Some long- term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, may continue after the IND is submitted. The IND and IRB ProcessesAn 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 ~~24of~~ **of** a request for an IND, applicants must submit a protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, the results of the nonclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. The FDA requires a 30- day waiting period after receiving an IND before the corresponding clinical trial may begin. This waiting period is designed to allow the FDA to review the IND to determine whether human research subjects may be exposed to unreasonable health risks. At any time during this 30- day period, the FDA may raise concerns or questions about the conduct of the clinical trials as outlined in the IND and impose a clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. Following commencement of a clinical trial under an IND, the FDA may also place a clinical hold or partial clinical hold on that clinical trial at any time. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. For example, a specific protocol or part of a protocol is not allowed to proceed, while other protocols may do so. No more than 30 days after imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor a written explanation of the basis for the hold. Following issuance of a clinical hold or partial clinical hold, an investigation may only resume after the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed. In addition to the foregoing IND requirements, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB' s requirements or if the product candidate has been associated with unexpected serious harm to patients. A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all FDA IND requirements must be met unless waived. When the foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with FDA certain regulatory requirements in order to use the study as support for an IND or application for marketing approval. In particular, such studies must be conducted in accordance with GCP, including review and approval by an independent ethics committee, or IEC, and informed consent from subjects, and must meet other clinical trial requirements, such as sufficient patient population size and statistical powering. The FDA must be able to validate the data through an onsite inspection, if deemed necessary by the FDA. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a clinical trial may move forward at designated check points based on access that only the group maintains to available data from the study. Suspension or termination of development during any phase of clinical trials can occur if it is determined that the participants or patients are being exposed to an unacceptable health risk. Other reasons for suspension or termination may be made by the clinical trial sponsor based on evolving business objectives and / or competitive climate. Information about certain clinical trials, including details of the protocol and eventually study results, also must be submitted within specific timeframes to the National Institutes of Health for public dissemination on the ClinicalTrials. gov data registry. Information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in some cases for up to two years after the date of completion of the trial. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give **22** rise to civil monetary penalties and may prevent the non- compliant party from receiving future grant funds from the federal government. The NIH' s Final Rule on ClinicalTrials. gov registration and reporting requirements became effective in 2017, and the government has brought enforcement actions against non- compliant clinical trial sponsors. Human Clinical Trials in Support of an NDAClinical 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 ~~25written~~ -- **written** study protocols detailing, among other things, study objectives, participant inclusion and exclusion criteria, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each phase of a clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined: ● Phase I.

The product candidate is initially introduced into healthy human subjects or, in certain indications such as cancer, patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage. ● Phase II. The product candidate is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. ● Phase III. The product candidate is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well- controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk- benefit profile of the product and to provide adequate information for the labeling of the product. Post- approval trials, sometimes referred to as Phase IV clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long- term safety follow up. In certain instances, the FDA may mandate the performance of Phase IV clinical trials as a condition of approval of an NDA. In the Consolidated Appropriations Act for 2023, Congress amended the FDCA to require sponsors of a Phase III clinical trial, or other " pivotal study " of a new drug to support marketing authorization, to submit a diversity action plan for such clinical trial. The action plan must include the sponsor' s diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. A sponsor must submit a diversity action plan to FDA by the time the sponsor submits the trial protocol to the agency for review. The FDA may grant a waiver for some or all of the requirements for a diversity action plan. It is unknown at this time how the diversity action plan may affect Phase III trial planning and timing or what specific information FDA will expect in such plans, but if FDA objects to a sponsor' s diversity action plan and requires the sponsor to amend the plan or take other actions, it may delay trial initiation. Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the case of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase I, Phase II and Phase III clinical trials might not be completed successfully within any specified period, or at all. Furthermore, the FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB' s requirements or if the drug has been associated with unexpected serious harm to patients. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted. Concurrent with clinical trials, companies often complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, must develop methods for testing the identity, strength, quality, and purity of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life. **23** Traditional and Section 505 (b) (2) NDAsNDAs for most new drug products are based on two adequate and well- controlled, or pivotal, clinical trials that must contain substantial evidence of the safety and efficacy of the proposed new product. These applications are submitted under Section 505 (b) (1) of the FDCA. The FDA is, however, authorized to approve an alternative type of NDA under Section 505 (b) (2) of the FDCA. This type of application allows the applicant to rely, in part, on the FDA' s previous findings of safety and efficacy for a drug product previously ~~26approved~~ **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 FDAAssuming successful completion of required clinical testing and other requirements, the results of the preclinical studies and clinical trials, together with detailed information relating to the product' s chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. Under federal law, the submission of most NDAs is subject to a substantial user fee. The sponsor of an approved NDA is also subject to an

annual prescription drug program fee. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for drugs with orphan designation and a waiver for certain small businesses submitting their first human drug applications for review. Eyenovia is currently eligible for a waiver of the application fees under the small business provisions. The FDA conducts a preliminary review of an NDA within 60 days of its receipt and informs the sponsor by the 74th day after the FDA' s receipt of the submission to determine whether the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in- depth substantive review. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has agreed to certain performance goals in the review process of NDAs. For most applications involving new molecular entities, the FDA has 10 months from the date of filing in which to complete its initial review of a standard application and respond to the applicant, and six months from the date of filing for an application with " priority review. " Even if the NDA is filed by the FDA, however, companies cannot be sure that any approval will be granted on a timely basis, if at all. Moreover, the FDA does not always meet its PDUFA goal dates, and the review process for both standard and priority new drug applications may be extended by the FDA for various reasons, including for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission. Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre- approval inspections may cover all facilities associated with an NDA submission, including drug component manufacturing (such as active pharmaceutical ingredients), finished drug product manufacturing, and control testing laboratories. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. The FDA may refer an application for a novel drug product to an advisory committee. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation **24** 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. ~~27Fast~~ -- **Fast** Track, Breakthrough Therapy and Priority Review DesignationsThe FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life- threatening disease or condition. These programs are fast track designation, breakthrough therapy designation and priority review designation. Specifically, the FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life- threatening disease or condition, and it demonstrates the potential to address unmet medical need by providing a therapy where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. For fast track products, sponsors may have more frequent interactions with the FDA and the FDA may initiate review of sections of a fast track product' s NDA before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA' s time period goal for reviewing a fast track application does not begin until the last section of the NDA is submitted. In addition, the fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process. The FDA may grant breakthrough therapy designation to a drug or biologic meeting certain statutory criteria upon a request made by the IND sponsor. A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other drugs, to treat a serious or life- threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross- disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner. In addition, breakthrough therapies are eligible for accelerated approval of their respective marketing applications. The FDA may designate a product for priority review if it is a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines at the time that the marketing application is submitted, on a case- by- case basis, whether the proposed drug represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment- limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA' s goal for taking action on a marketing application from 10 months to six months for an new molecular entity NDA from the date of filing. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, fast track designation, breakthrough therapy designation, and priority review do not change the scientific or medical standards for approval or the quality of evidence necessary to support approval but may expedite the development or review process. Accelerated Approval PathwayThe 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 **25** is subject to rigorous post- marketing compliance requirements, including the completion of Phase IV or post- approval clinical trials to ~~28confirm --~~ **confirm** the effect on the clinical endpoint. Failure to conduct required post- approval studies, or confirm a clinical benefit during post- marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis. As part of the Consolidated Appropriations Act for 2023, Congress provided FDA additional statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval. Under the act' s amendments to the FDCA, FDA may require the sponsor of a product granted accelerated approval to have a confirmatory trial underway prior to approval. The sponsor must also submit progress reports on a confirmatory trial every six months until the trial is complete, and such reports are published on FDA' s website. The amendments also give FDA the option of using expedited procedures to withdraw product approval if the sponsor' s confirmatory trial fails to verify the claimed clinical benefits of the product. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA. The FDA' s Decision on an NDAThe 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 DrugsDrugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fee requirements for any marketed products, as well as new application fees for supplemental applications with clinical data. In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic announced or unannounced inspections by ~~29the --~~ **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 **26** 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 DrugsIn 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 ~~30application~~ -- **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. **27** 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 StayUpon 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; ~~31III --~~ **III** . the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; orIV. the listed patent is invalid, unenforceable or will not be infringed by the manufacture, use or sale of the new product. **28** 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 ExclusivityUnder 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, ~~32but --~~ **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 ExtensionA 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 **29** 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 DevicesMedical devices are strictly regulated by the FDA in the United States. Under the FDCA a medical device is defined as " an instrument, apparatus, implement, machine, contrivance, implant,- in vitro- reagent, or other similar or related article, including a component, part or accessory which is, among other things: intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes. " This definition provides a clear distinction between a medical device and other FDA regulated products such as drugs. If the primary intended use of a medical product is achieved through chemical action or by being metabolized by the body, the product is a drug or biologic. If not, it is generally a medical device. Unless an exemption applies, a new medical device may not be marketed in the United States unless and until it has been cleared through the premarket notification, or 510 (k) process or approved by the FDA pursuant to a premarket approval application, or PMA. The information that must be submitted to the FDA in order to obtain clearance or approval to market a new medical device varies depending on how the medical device is classified by the FDA. Medical devices are classified into one of three classes on the basis of the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I devices are those low risk devices for which reasonable assurance of safety and effectiveness can be provided by adherence to the FDA' s general controls for medical devices, which include applicable portions of the FDA' s Quality System Regulation, or QSR; facility registration and product listing; reporting of adverse medical events and malfunctions; and appropriate, truthful and non- misleading labeling, advertising and promotional materials. Most Class I devices are exempt from premarket regulation; however, some Class I devices require premarket clearance by the FDA through the 510 (k) process. Class II devices are moderate risk devices and are subject to the FDA' s general controls, and any other special controls, such as performance standards, post- market surveillance, and FDA guidelines, deemed necessary by the FDA to provide reasonable assurance of the devices' safety and effectiveness. Premarket review and clearance by the FDA for most Class II devices is accomplished through the 510 (k) process, although some Class II devices are exempt from the 510 (k) requirements. To obtain 510 (k) clearance, a sponsor must submit to the FDA a premarket notification demonstrating that the device is substantially equivalent to a device that is already legally marketed in the United States and for which a PMA is not required (i. e., a Class II device), including any device that was reclassified from Class III to Class I or II. The device to which the sponsor' s device is compared for the purpose of determining substantial equivalence is called a " predicate device. " The FDA' s goal is to make a substantial equivalence determination within 90 days of FDA' s receipt of the 510 (k) application, but it often takes longer if the FDA requests additional information. Most 510 (k) s do not require supporting data from clinical trials, but the FDA may request such data for certain devices. After a device receives 510 (k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new clearance or possibly a pre- market approval. Premarket notifications are subject to user fees unless a specific exemption applies. ~~33Class~~ -- **Class** III devices are deemed by the FDA to pose the greatest risk to patients, such as those for which reasonable assurance of the device' s safety and effectiveness cannot be assured solely by the general controls and special controls described above, and especially devices that are life- sustaining, life- supporting or implanted. All Class III devices must be reviewed and approved by the FDA through the PMA process. A PMA must be supported by extensive data including, but not limited to, technical, nonclinical testing, clinical trials, manufacturing and labeling to demonstrate to the FDA' s satisfaction the safety and effectiveness of the device for its intended use. After a PMA is sufficiently complete, the FDA will accept the application for filing and begin an in- depth review of the submitted information. By statute, the FDA has 180 days to review the accepted application, although review of the application generally can take between one and three years. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. Although the FDA is not bound by the advisory panel decision, it considers such recommendations when making final decisions on approval. In addition, the FDA will conduct **30** a preapproval inspection of the manufacturing facility to ensure compliance with the QSR. New PMA applications or PMA application supplements are also required for product modifications that affect the safety and efficacy of the device. PMA (and supplemental PMAs) are subject to significantly higher user fees than are 510 (k) premarket notifications. Medical device types that the FDA has not previously classified as Class I, II or III are automatically classified into Class III regardless of the level of risk they ultimately pose to patients and / or users. The Food and Drug Administration Modernization Act of 1997 established a new route to market for low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the " Request for Evaluation of Automatic Class III Designation, " or the De Novo classification procedure. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request that the FDA determine that the initial classification of its medical device is actually Class I or Class II based on a benefit- risk analysis demonstrating the device actually presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Under the most recent FDA premarket review goals, FDA will attempt to issue a decision on most De Novo

classification requests within 150 days of receipt. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the reclassification petition if it identifies a legally marketed predicate device that would be appropriate for a 510 (k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed. De Novo reclassification requests are also subject to user fees, unless a specific exemption applies. Post- Marketing Restrictions and EnforcementAfter a device is placed on the market, numerous regulatory requirements apply. These include, but are not limited to: ● submitting and updating establishment registration and device listings with the FDA; ● compliance with the QSR, which requires manufacturers to follow stringent design, testing, control, documentation, record maintenance, including maintenance of complaint and related investigation files, and other quality assurance controls during the manufacturing process; ● announced or unannounced routine or for- cause device facility inspections by the FDA, which may include our suppliers' facilities; and ● labeling regulations, which prohibit the promotion of products for uncleared or unapproved (or " off- label ") uses and impose other restrictions relating to promotional activities; ● corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections or removals if undertaken to reduce a risk to health posed by a device or to remedy a violation of the FDCA that may present a risk to health; and ● post- market surveillance regulations, which apply to certain Class II or III devices when necessary to protect the public health or to provide additional safety and effectiveness data for the device. Under the FDA medical device reporting, or MDR, regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or a similar device of such manufacturer were to ~~34recur~~ -- **recur** . The decision to file an MDR involves a judgment by the manufacturer. If the FDA disagrees with the manufacturer' s determination, the FDA can take enforcement action. The MDR requirements also extend to healthcare facilities that use medical devices in providing care to patients, or " device user facilities, " which include hospitals, ambulatory surgical facilities, nursing homes, outpatient diagnostic facilities, or outpatient treatment facilities, but not physician offices. A device user facility must report any device- related death to both the FDA and the device manufacturer, or any device- related serious injury to the manufacturer (or, if the manufacturer is unknown, to the FDA) within 10 days of the event. Device user facilities are not required to report device malfunctions that would likely cause or contribute to death or serious injury if the malfunction were to recur but may voluntarily report such malfunctions through MedWatch, the FDA' s Safety Information and Adverse Event Reporting Program. Additionally, the FDA has the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. The authority to require a recall must be based on an FDA finding that there is reasonable probability **31** 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 ProductsA 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; ~~35~~ ● 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 **32** 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. ~~36Review~~ -- **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 ChinaThe National Medical Products Administration (NMPA) is the main regulatory authority responsible for drug registration, review, and approval in China. NMPA' s Drug Evaluation Center (CDE) is responsible for the review of drug clinical trial applications and drug marketing authorization applications for overseas manufactured drugs. After completing the pre- clinical studies and clinical trials supporting the drug registration, the applicant submits the drug marketing authorization application according to the applicable **33** requirements. After the formal examination of the application materials, acceptance will be given if they meet the requirements. Pharmaceutical, medical, and other technical personnel of the CDE review the accepted drug marketing authorization applications. After a comprehensive review they issue a registration certificate of approval for the subject drug. The validity period of the drug registration certificate is five years. During the validity period the marketing authorization holder is responsible for the safety, effectiveness, and quality control of the approved drug and applies for drug re- registration six months prior to the expiration of the validity period. Procedures Governing Approval of Drug Products in KoreaThe Ministry of Food and Drug Safety (MFDS) is the main regulatory authority responsible for drug registration, review, and approval in South Korea. Under the MFDS, the Pharmaceutical Safety Bureau, and the National Institute of Food and Drug Safety Evaluation (NIFDS) are responsible for the review, approval, and regulation of pharmaceutical products. Pharmaceuticals that require data submission must submit safety and efficacy data for evaluation before receiving approval. This includes drug products that have new effectiveness, composition, or route of administration. The applicant will prepare the application dossier for drug approval. Submit the application to MFDS Management Division for Drug Approval & Review. The MFDS then conducts an initial assessment of the application, generates a report outlining the application dossier, and submits it to the MFDS Drug & Evaluation Department. The Drug & Evaluation department conducts a review of, among other things, the results of the initial assessment, technology, safety & efficacy data, product standards, clinical trial data, good manufacturing practice (GMP) data, Drug Master File (DMF) data, impacts on intrinsic (genetic) factors, and extrinsic (factors). If no further documentation or supplementary data is required, the MFDS issues the applicant a Certificate of Approval. ~~37Pharmaceutical~~ -- **Pharmaceutical** Coverage, Pricing and ReimbursementOur Mydcombi, MicroLine and clobetasol propionate product candidates are intended as " cash pay " and therefore are not likely subject to the significant uncertainty that exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. The sales of MicroPine, however, would likely depend in part on the extent to which third- party payors, including government health programs in the United States such as Medicare and Medicaid,

commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, such products. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third- party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication. In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third- party payors to reimburse all or part of the associated healthcare costs. Patients and healthcare providers are unlikely to use our products unless third- party payor coverage is provided and reimbursement by such payor is adequate to cover a significant portion of the cost of our products. Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other comparable government authorities. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third- party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for the product. In the United States, no uniform policy of coverage and reimbursement for drug products exists among third- party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third- party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost- effectiveness of medical products and services and imposing controls to manage costs. Third- party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication. Moreover, for products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used. In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost- effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Obtaining coverage and reimbursement approval of a product from a government or other third- party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost- effectiveness data for the use of our products on a payor- by- payor basis, with no assurance that **34** 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. ~~38The~~ -- **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 RegulationHealthcare 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; **35** ● 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; ~~39~~ ● the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or the Affordable Care Act, which requires manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians, certain advanced non-physician healthcare practitioners, and teaching hospitals or to entities or individuals at the request of, or designated on behalf of, the physicians, advanced healthcare practitioners and teaching hospitals as well as certain ownership and investment interests held by physicians and their immediate family members; and ● analogous state and foreign laws and regulations, such as state anti- kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services that are reimbursed by non- governmental third- party payors, including private insurers. The majority of states also have statutes or regulations similar to the aforementioned federal laws, some of which are broader in scope and apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to clinicians and other healthcare providers or marketing expenditures. Some states and local jurisdictions require the registration of pharmaceutical sales representatives. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Because of the breadth of these laws and the narrowness of their exceptions and safe harbors, it is possible that business activities can be subject to challenge under one or more of such laws. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring that business arrangements with third parties comply with applicable healthcare laws and regulations is costly and time consuming. If business operations are found to be in violation of any of the laws described above or any other applicable governmental regulations a pharmaceutical manufacturer may be subject to penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in governmental funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with these laws, and curtailment or restructuring of operations, any of which could adversely affect a pharmaceutical manufacturer' s ability to operate its business and the results of its operations. Changes in the Healthcare MarketplaceThe United States and some foreign jurisdictions are considering enacting or have enacted a number of additional legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our product candidates profitably, if approved. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we otherwise may have obtained and we **36** 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 ~~40often~~ -- **often** follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payors. In March 2010, the United States Congress enacted the Affordable Care Act, which, among other things, included changes to the coverage and payment for products under government health- care programs. The Affordable Care Act included provisions of importance to our potential product candidate that: ● created an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs products, apportioned among these entities according to their market share in certain government healthcare programs; ● expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 138 % of the federal poverty level, thereby potentially increasing a manufacturer' s Medicaid rebate liability; ● expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of " average manufacturer price, " or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices; ● addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; ● expanded the types of entities eligible for the 340B drug discount program; ● established the Medicare Part D coverage gap discount program by requiring manufacturers to provide point- of- sale- discounts off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D; and ● created a new Patient- Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. Following several years of litigation in the federal courts, in June 2021, the U. S. Supreme Court upheld the Affordable Care Act when it dismissed a legal challenge to the Affordable Care Act' s constitutionality. Further legislative and regulatory changes under the Affordable Care Act remain possible, although it is unknown what form any such changes or any law would take, and how or whether it may affect the pharmaceutical and medical device industries as a whole or our business in the future. We expect that changes or additions to the Affordable Care Act, the Medicare and Medicaid programs and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry in the United States. The Biden Administration has indicated that lowering prescription drug prices is a priority. For example, in July 2021, President Biden issued a sweeping executive order on promoting competition in the American economy that includes several mandates pertaining to the pharmaceutical and healthcare insurance industries, and called on HHS to release a comprehensive plan to combat high prescription drug prices. The drug pricing plan released by HHS in September 2021 in response to the executive order makes clear that the Biden Administration supports aggressive action to address rising drug prices, including allowing HHS to negotiate the cost of Medicare Part B and D drugs. It is unclear how other healthcare reform measures of the Biden administration will impact healthcare laws and regulations or our business. **37** Other legislative changes have been proposed and adopted since passage of the ACA that affect healthcare expenditures. These changes include aggregate reductions to Medicare payments to providers of up to 2 % per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and was extended by the Consolidated Appropriations Act for 2023, and will remain in effect through 2032 unless additional Congressional action is taken. There has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries, presidential executive orders and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products. Government authorities and other third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products and services, implementing reductions in Medicare and other healthcare funding and ~~41applying~~ -- **applying** new payment methodologies. In addition to the sweeping reforms contained in the ACA, other legislative changes have been proposed and adopted in the United States that may affect healthcare expenditures. For example, the 2020 Consolidated Appropriations Act (P. L. 116- 94) included a piece of bipartisan legislation called the Creating and Restoring Equal Access to Equivalent Samples Act, or the CREATES Act. The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS program for certain products, to deny generic product developers access to samples of brand products. Because generic product developers need samples to conduct certain comparative testing required by the FDA, some have attributed the inability to timely obtain samples as a cause of delay in the entry of generic products. To remedy this concern, the CREATES Act establishes a private cause of action that permits a generic product developer to sue the brand manufacturer to compel it to furnish the necessary samples on " commercially reasonable, market- based terms. " Whether and how generic product developments will use this new pathway, as well as the likely outcome of any legal challenges to provisions of the CREATES Act, remain highly uncertain and its potential effects on our future commercial products are unknown. More recently, in August 2022, President Biden signed into the law the Inflation Reduction Act of 2022, or the IRA. Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. Starting in 2023, a manufacturer of a drug or biological product covered by Medicare Parts B or D must pay a rebate to the federal government if the drug product' s price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting in payment

year 2026, CMS will negotiate drug prices annually for a select number of single- source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. Further, in December 2020, the U. S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmacy benefit managers, or PBMs, and other members of the healthcare and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area. The Federal Trade Commission in mid- 2022 also launched sweeping investigations into the practices of the PBM industry that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. Significant efforts to change the PBM industry as it currently exists in the United States may affect the entire pharmaceutical supply chain and the business of other stakeholders, including pharmaceutical developers like us. We expect that federal, state and local governments in the United States, as well as foreign governments, will continue to consider legislation directed at lowering the total cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize any product that is ultimately approved, if approved. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. Human Capital ResourcesAs of March 15, ~~2024~~ **2025** , we had ~~57~~ **14** total employees. **Thirteen** ~~All 57~~ are full- time employees and **one is** ~~there are no~~ part- time ~~employees~~ . We also engage various consultants and contractors. **38** We consider our relations with our employees to be good. To successfully ~~commercialize~~ **develop** our product candidates, we must be able to attract and retain highly skilled personnel. We ~~anticipate hiring additional employees during 2024. We~~ continually evaluate the business need and opportunity and balance in- house expertise and capacity with outsourced expertise and capacity. **We** ~~Currently, we outsource substantial clinical trial work to clinical research organizations and manufacturing to contract manufacturers. 42We~~ believe that our future success largely depends upon our continued ability to attract and retain highly skilled employees. Biotechnology and pharmaceutical companies both large and small compete for a limited number **of** qualified applicants to fill specialized positions. To attract qualified applicants, we offer a total rewards package potentially consisting of base salary and cash target bonus, a comprehensive benefit package and equity compensation. Bonus opportunity and equity compensation increase as a percentage of total compensation based on level of responsibility. Actual bonus payout is based on performance. Much of our success is rooted in the diversity of our teams and our commitment to inclusion. We value diversity at all levels. We believe that our business benefits from the different perspectives a diverse workforce brings, and we pride ourselves on having a strong, inclusive and positive culture based on our shared mission and values. Information About Our Directors and Executive OfficersName ~~PositionTsontcho~~ **PositionCharles Mather IVChairman and Director of EyenoviaTsontcho** Ianchulev, M. D., M. P. H. ~~Chairman and~~ Director of EyenoviaMichael GeltzeilerDirector of EyenoviaRachel Jacobson ~~Director of Eyenovia and President of the Drone Racing League (DRL) Charles Mather~~ Director of Eyenovia Ram Palanki, Pharm. D. Director of Eyenovia and Executive Vice President of Commercial Strategy & Operations at REGENXBIO Inc. Ellen Strahlman, M. D., MHScDirector of EyenoviaMichael RoweChief Executive Officer **, Principal** ~~and Director of EyenoviaJohn GandolfoChief~~ Financial Officer and ~~Secretary~~ **Director** of EyenoviaBren KernChief Operating **OfficerAvailable** ~~Officer of Eyenovia Available~~ InformationOur 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 CAPITALWe ~~might~~ **will need to raise additional capital to remain a going concern, which may** not be ~~able~~ **available on acceptable terms, or at all. We require significant capital resources in order** to continue ~~as a going concern, which would likely cause our stockholders~~ to **operate** ~~lose most or~~ **our** ~~all~~ **business and conduct our exploration** of ~~their investment~~ **strategic alternatives, and our limited liquidity could materially and adversely affect our business operations** . **As of** ~~Our audited financial statements for the year ended~~ December 31, ~~2023~~ **2024** ~~were prepared~~ **, we had cash and cash equivalents of $ 2. 1 million. As of March 15, 2025, we owed $ 10. 2 million in principal and accrued interest** under the ~~assumption that~~ **Loan and Security Agreement. As of December 31, 2024,** we ~~would~~ **had an accumulated deficit of approximately $ 195. 3 million. We expect to** continue **to incur cash outflows from operations for** ~~as a going concern. However, we have concluded that there~~ -- **the** ~~is~~ **near future. These circumstances raise** substantial doubt about our ability to continue as a going concern **for at least one year from the date this Form 10- K was filed** , ~~therefore~~ **and** our independent registered public accounting firm included a " going concern " explanatory paragraph in its report on our financial statements for the year ended December 31, ~~2023~~ **2024** , indicating that, without additional sources of funding, our cash at December 31, ~~2023~~

2024 is not sufficient for us to operate as a going concern for a period of at least one year from the date that the financial statements included in this Annual Report on Form 10- K are issued. Management' s plans concerning these matters, including our need to raise additional capital, are described in Note 2 ~~—~~ **-** Summary of **39** Significant Accounting Policies ~~—~~ **-** Liquidity and Going Concern of our financial statements included within this Annual Report on Form 10- K. **Implementation of** ~~However, management cannot assure you that~~ our plans **and our ability** to ~~raise~~ **continue as a going concern will depend on many factors, including our ability to successfully commercialize our products and services, competing technological and market developments, and the need to enter into collaborations with other companies. Also, it is very difficult to project our current monthly cash burn rate given the transitional status of the Company and this estimate may prove inaccurate and we may expend our limited resources sooner. The** additional capital ~~will~~ **we require in order to remain a going concern may not** be **available on reasonable terms, if at all, due to a variety of factors, including uncertainty about the future direction of the Company, as well as broader conditions in the economy and capital markets, including recent volatility caused by inflation, questions about bank stability and other factors. If we are** ~~successful~~ **unsuccessful in our operations to secure additional financing, or if any such incremental financing is not sufficient to fund our operations, we may be required to take additional measures to reduce costs in order to conserve our cash, pursue strategic transactions or file for bankruptcy** . If we cannot continue as a viable entity, our stockholders would likely lose most or all of their investment in us. ~~43We~~ **Our ongoing exploration of alternative strategic paths may not result in entering into or completing transactions when necessary, and the process of reviewing alternative strategic paths or their conclusion could adversely affect our stock price. We continue to evaluate strategic paths to provide the resources necessary to commercialize Mydcombi and maximize stockholder value. Potential strategic paths may include partnerships, joint ventures, mergers, acquisitions or licensing transactions, a combination of these, or other strategic transactions. There can be no assurance, however, that our evaluation** will **result** ~~need to raise additional capital~~ in **transactions** ~~order to continue developing our~~ **or other alternatives** ~~product candidates and to manufacture and commercialize them as well as Mydcombi and clobetasol propionate~~ , **even when deemed necessary** ~~currently our only FDA- approved commercial products~~ . ~~Such funding might~~ **There is no set timetable for our strategic process and we do** not **intend to provide updates unless or until the Board of Directors approves a specific action or otherwise determines that disclosure is appropriate or necessary. Any potential transaction would** be ~~available~~ **dependent** on ~~acceptable~~ **a number of factors that may be beyond our control, including, among other things, market conditions, industry trends, the interest of third parties in a potential transaction with us, obtaining stockholder approval, where necessary, and the availability of financing to third parties in a potential transaction with us on reasonable** terms **. The process of reviewing alternative strategic paths may be time consuming and may involve the dedication of significant resources and may require us to incur significant costs and expenses. It could negatively impact our ability to attract** , **retain and motivate employees, and expose us to potential litigation in connection with this process or any resulting transaction. If we are unable to effectively manage the process, our financial condition and results of operations could be adversely affected. In addition, speculation regarding any developments related to the review of strategic alternatives and perceived uncertainties related to the future of our Company could cause our stock price to fluctuate significantly. Further, any alternative strategic paths that may be pursued and completed ultimately may not deliver the anticipated benefits or enhance stockholder value. There can be no guarantee that the process of evaluating alternative strategic paths will result in our Company entering into or completing potential transactions within the anticipated timing** or at all. ~~Failure to obtain this necessary capital~~ **Delisting could prevent us from maintaining an active, liquid and orderly trading market for our common stock and** may **materially and adversely impact** ~~force us to delay, limit or~~ **our** ~~terminate~~ **ability to consummate** certain ~~of~~ **strategic transactions. Our ability to publicly** ~~our~~ **or** ~~product development~~ **privately sell equity securities** and ~~commercialization efforts~~ **the liquidity of** ~~or~~ **our common stock could** ~~to continue operations. We require substantial additional funding to continue our research and development activities. We also need substantial funding to advance 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 manufacture and market any products that are or may~~ be **adversely affected** ~~approved for commercial sale. Even~~ if we are ~~successful in raising additional~~ **delisted from The Nasdaq** ~~capital~~ **Capital Market or if we are unable to transfer our listing to another stock market. On September 18** , ~~such funds~~ **2024, we were notified by The Nasdaq Stock Market LLC, or Nasdaq, that we were in breach of Listing Rule 5550 (a) (2), or the (" Minimum Bid Price Rule "), for continued listing on the Nasdaq Capital Market because the minimum bid price of our listed securities for 30 consecutive business days had been less than $ 1 per share. On December 12, 2024, we received a letter from Nasdaq notifying us that, because the closing bid price for our common stock was below $ 0. 10 per share for 10 consecutive trading days, we were in breach of Listing Rule 5810 (c) (3) (A) (iii). On January 31, 2025, we executed an 80- for- 1 reverse stock split, following which we were notified by Nasdaq that we had regained compliance with the Minimum Bid Price Rule. Nasdaq Listing Rule 5810 (c) (3) (A) (iv) states that any listed company that fails to meet the Minimum Bid Price Rule and has effected a reverse stock split over the prior one- year period, or has effected one or more reverse stock splits over the prior two- year period with a cumulative ratio of 250 shares or more to one, will not be eligible for an automatic 180- day grace compliance period and the Nasdaq Listing Qualifications Department is obligated to immediately issue a delisting determination. Therefore, if we were to fall out of compliance with the Minimum Bid Price requirement prior to January 31, 2026, we would not be able to effect a reverse stock split and would immediately be issued a delisting determination. If our**

common stock is delisted by Nasdaq, it could lead to a number of negative implications, including an adverse effect on the price of our common stock, deterring broker- dealers from making a market in or otherwise seeking or generating interest in our 40 common stock, increased volatility in our common stock, reduced liquidity in our common stock, the loss of federal preemption of state securities laws and greater difficulty in obtaining financing. Delisting could also cause a loss of confidence of our customers, collaborators, vendors, suppliers and employees, which could harm our business and future prospects. If our common stock is delisted by Nasdaq, the price of our common stock may **decline** ~~prove to be insufficient for these activities. Our financing needs may change substantially because of research and development~~ , ~~manufacturing~~ and **although** ~~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~~ **our common stock** may be ~~outside of~~ **eligible to trade on the OTC Bulletin Board, another over- the- counter quotation system,** ~~our~~ **or on** ~~control, including: ● the~~ ~~resources~~ **pink sheets** , ~~time and~~ **an investor may find it more difficult to dispose of their common stock or obtain accurate quotations as to the market value of our common stock. If our common stock is delisted from Nasdaq, trading in our securities may be subject to the SEC' s " penny stock " rules. These " penny stock " rules will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our common stock. The additional burdens imposed upon broker- dealers by these requirements may discourage broker- dealers from recommending transactions in our securities, which could severely limit the liquidity of our securities and consequently adversely affect the market price for our securities. Furthermore, if our common stock is delisted, we would expect it to have an adverse impact on our ability to consummate certain strategic alternatives. Further, if our common stock is delisted, we would incur additional** costs **under state blue sky laws** ~~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 **connection with** ~~our research and development programs; ● the timing, receipt and amount of milestone, royalty and other payments from~~ any ~~current~~ **sales of** ~~or~~ **our securities** ~~future collaborators, if any; and ● costs necessary to protect our intellectual property~~ . ~~If our estimates and predictions relating to any of these~~ **These requirements could severely limit the market liquidity of** ~~factors are incorrect, we may need to modify our operating plan. Additional funds might not be available to us on acceptable terms, or~~ **our** ~~at all, when needed~~ **common stock and the ability of our stockholders to sell our common stock in the secondary market** . Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies ~~. Until such time as we can generate substantial product revenues, as to which we can make no assurance, we intend to finance our cash needs through equity offerings, debt financings, government and / or other third- party grants or other third- party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements~~ . To the extent that we raise additional capital through the sale of equity or convertible debt securities, our investors' ownership interest will be diluted. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail ~~one or more clinical research or development programs~~ or delay manufacturing and commercialization plans, which would adversely impact potential revenues, results of operations and our financial condition. If we raise additional capital through future collaborations, strategic alliances or third- party licensing arrangements, we may have to relinquish valuable rights to our intellectual property, future revenue streams, ~~research programs,~~ Mydcombi, **Optejet or** clobetasol propionate ~~or product candidates~~ , or grant licenses on terms that might not be favorable to us. ~~44The~~ -- **The** terms of ~~our~~ **the** Loan and Security Agreement ~~with Avenue Capital Management II, L. P. and the lenders listed therein~~ require us to meet certain operating covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business. On November 22, 2022, we entered into ~~a~~ **the** Loan and Security Agreement with Avenue ~~Capital Management II~~ , **which** ~~L. P. and related entities (together, " Avenue ") (the " Loan and Security Agreement ") that~~ is secured by a lien on all of our assets **. The Loan and Security Agreement, as supplemented by the Supplement, provides for term loans in an aggregate principal amount of up to $ 15. 0 million to be delivered in multiple tranches** . The Loan and Security Agreement contains customary affirmative and negative covenants and events of default. Affirmative covenants include, among others, covenants requiring us to protect and maintain our intellectual property and comply with all applicable laws, deliver certain financial reports and maintain insurance coverage. Negative covenants include, among others, covenants restricting us from transferring any part of our business or intellectual property, incurring additional indebtedness, engaging in mergers or acquisitions, repurchasing shares, paying dividends or making other distributions, making investments, and creating other liens on our assets, including our intellectual property, in each case subject to customary exceptions. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility. These restrictions may include, among other things, limitations on the incurrence of additional debt and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem capital stock or make investments. If we default under the terms of the Loan and Security Agreement or any future debt facility, Avenue may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. Further, if we were to be liquidated, Avenue' s right to repayment would be senior to the rights of the holders of our common stock. Avenue could declare an event of default upon the occurrence of any event that could reasonably be expected to result in what they interpret as a material adverse effect as defined under the Loan and Security Agreement. Any declaration by Avenue of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. We have **entered into a loan modification agreement with Avenue and, based on our lack of financial liquidity, we cannot guarantee that we will be able to comply with the terms of this agreement, or continue obtaining**

forbearance if needed. As of March 15, 2025, the Company owed $ 10. 2 million in principal and accrued interest under the facility. Amounts outstanding under the facility bear interest at an annual rate equal to the greater of (a) 7. 0 % and (b) the prime rate as reported in The 41 Wall Street Journal plus 4. 45 % (the " Interest Rate "). The maturity date is November 1, 2025. On November 22, 2024, the Company entered into the First Amendment, pursuant to which Avenue agreed to defer principal and interest payments on amounts outstanding until February 28, 2025. On February 21, 2025, the Company entered into the Second Amendment, pursuant to which Avenue agreed to defer principal and interest payments on amounts outstanding until the end of September 2025. Deferred interest will accrue on the outstanding principal amount at the interest rate as defined in the Second Amendment. Under the Second Amendment, the Company has agreed to use a portion of the proceeds (net of fees and commissions payable to Chardan) received from sales under its Amended and Restated Sales Agreement (the " ATM Agreement ") with Chardan Capital Markets, LLC for its at- the- market offering program (the " ATM Proceeds ") to pay down the outstanding principal amount under the Loan and Security Agreement as follows: a) until the Company raises $ 3 million of aggregate ATM Proceeds, 65 % of the ATM Proceeds shall be remitted to Avenue as a payment in respect of the outstanding principal amount, and b) after the Company raises $ 3 million of aggregate ATM Proceeds, 75 % of the ATM Proceeds shall be remitted to Avenue as a payment in respect of the outstanding principal amount. Under the Second Amendment, at any time on or after April 1, 2025, Avenue will also have the right, in their discretion, but not the obligation, to convert an aggregate amount of up to $ 10 million of the aggregate principal amount under the Loan and Security Agreement into shares of the Company' s common stock, at a price equal to $ 1. 68 per share. It is possible that the Company may be unable to make payments against the loan when the forbearance period ends on September 30, 2025. If the Company fails to obtain the requisite waivers or further extends the forbearance period, Avenue could declare the Company in default and require repayment of the outstanding balances on the relevant loans. If that were to occur, the Company may not have sufficient funds to pay the applicable debt. We currently do not have sufficient liquidity to repay all the outstanding debt to Avenue. We have incurred operating losses since our inception. We expect to continue to incur losses for the foreseeable future and might never achieve or maintain profitability. We have incurred net losses of approximately $ ~~145~~ **195** . ~~5~~ **3** million since inception, have not generated any significant product sales revenue and have not achieved profitable operations. Our net losses were approximately $ **49. 8 million and $** 27. 3 ~~million and $ 28. 0~~ million for the years ended December 31, **2024 and** 2023 ~~and 2022~~ , respectively. We expect to continue to incur substantial losses in future periods while we continue to test and prepare our product candidates for the market. **We may** ~~It could be a year or more, if ever~~ **never** ~~, before we~~ achieve profitability. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if, and as, we: ● continue ~~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 Mydcombi, clobetasol propionate and any other~~ -- **the Optejet ® User Filled Device** ~~product candidate for which we may obtain marketing approval~~ ; ● develop, maintain, expand and protect our intellectual property portfolio; **and** ● implement additional operational, financial and management ~~systems~~ **systemsEven** ~~; ● 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 substantial revenues from the sale of our ~~potential products~~ **product** , we might not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations. Even if we do achieve profitability, we might not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital ~~, 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. 45Our 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 commenced active operations in 2014, and 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 Arctic Vision, for the development and commercialization of MicroPine, MicroLine and MydcombiTM in Greater China and South Korea, and Senju, for the development and commercialization of MicroPine, MicroLine and Mydcombi in Asia (other than Greater China and South Korea). Other than FDA approval of Mydcombi and clobetasol propionate, 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, ~~2023~~ **2024** , we had federal net operating loss carry- forwards of approximately $ ~~104~~ **133** . ~~3~~ **7** million, of which approximately $ 10. 8 million will expire at various dates from 2034 to 2037 for federal purposes. If we are unable to use carryforward tax losses to reduce our future taxable basis for corporate tax purposes, our business, results of operations and financial condition may be adversely affected. Net operating loss and tax credit carry- forwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities and may become subject to an annual limitation in the event of certain

cumulative changes in the ownership interest of significant stockholders over a three- year period in excess of 50 %, as defined under Sections 382 and 383 of the Internal **42** 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. ~~46RISKS~~ -- **RISKS** RELATED TO ~~DEVELOPMENT~~ **THE PROPOSED BUSINESS COMBINATION BETWEEN EYENOVIA** AND **BETALIQThe proposed business combination may not be consummated on the terms described in the non- binding Letter of Intent or at all. On March 18, 2025, Eyenovia entered into the non- binding Letter of Intent with Betaliq, a privately- held company, relating to a proposed business combination between Eyenovia and Betaliq. Although Eyenovia anticipates entering into and closing a definitive business combination agreement in the second quarter of 2025, no assurance can be given that Eyenovia will be able to do so within that timeframe or at all. Execution of a definitive business combination agreement with Betaliq is subject to a number of conditions in the Letter of Intent, including satisfactory completion of due diligence by each party, which due diligence has not been completed as of the date of this report, as well as successful negotiation of the terms and conditions of the business combination agreement. In addition, even if Eyenovia were to negotiate and enter into the definitive business combination agreement, there is no assurance that the proposed business combination would be consummated on the terms described in the Letter of Intent, or at all. Failure to enter into a definitive business combination agreement or consummate the proposed business combination could negatively affect Eyenovia' s business, future business and financial results. The terms of a definitive business combination agreement are subject to negotiation, and Eyenovia cannot guarantee that the parties will be able to reach acceptable terms. Execution of the definitive business combination agreement is subject to various conditions in the Letter of Intent, including satisfactory completion of due diligence by each party. In the event the parties are unable to negotiate a definitive business combination agreement or consummate the proposed business combination, it will have a material adverse effect on Eyenovia' s business, financial condition, and results of operations, including the following: ● Incurring costs related to the negotiation of the business combination agreement, such as legal, accounting, and financial advisory fees; ● Declines in the market price of Eyenovia Common Stock to the extent that such market price reflects an assumption that the business combination would be consummated; ● The diversion of management' s attention from day- to- day business operations and the potential disruption to each company' s employees and other personnel and business relationships during the period the definitive business combination agreement is being negotiated and stockholder approval is being solicited; and ● The potential for litigation related to the proposed business combination. Even if the parties are able to enter into a definitive business combination agreement, Eyenovia cannot guarantee that the terms will be as described in the Letter of Intent or that the closing conditions set forth in such business combination agreement, including obtaining the requisite stockholder approval and listing the combined company' s shares on Nasdaq, will be satisfied. If Eyenovia is unable to satisfy its closing conditions, or if other mutual closing conditions are not satisfied, Betaliq will not be obligated to complete the business combination. If the business combination is not completed, Eyenovia' s board of directors would need to evaluate other available strategic alternatives, which alternatives may not be as favorable to Eyenovia stockholders as the business combination or available at all and could include winding down its operations, which may result in a total loss of stockholders' investment. 43 Eyenovia and Betaliq will be subject to various uncertainties while the proposed business combination is pending that could adversely affect the anticipated benefits of the business combination. Uncertainty about the effect of the proposed business combination on counterparties to contracts, employees, consultants, and other parties may have an adverse effect on Eyenovia and Betaliq. These uncertainties could cause contract counterparties and others who deal with Eyenovia or Betaliq to seek to change existing business relationships and may impair the ability of Eyenovia and Betaliq to attract, retain, and motivate key personnel until the business combination is completed and for a period of time thereafter. Retention and recruitment of employees and consultants may be particularly challenging prior to the completion of the business combination. Eyenovia employees and consultants, and the employees and consultants and prospective employees and consultants of Betaliq, may experience uncertainty about their future roles following the business combination. The negotiations to enter into a definitive business combination agreement, pursuit of the business combination, and the preparation for the combination of the two companies may place a significant burden on management and internal resources. Any significant diversion of management attention away from ongoing business and any difficulties encountered in the negotiations, transition, and integration process could affect each party' s business and limit them from pursuing attractive business opportunities and making other changes to their business prior to the entry into a definitive business combination agreement and / or completion of the business combination. Eyenovia expects to incur substantial transaction costs in connection with the proposed business combination. Eyenovia expects to incur a significant amount of non- recurring expenses in connection with the proposed business combination, including legal, accounting, financial advisory, consulting, printing, mailing, and other expenses. In general, these expenses are payable by Eyenovia whether or not the business combination is completed. Additional unanticipated costs may be incurred following consummation of the business combination. RISKS RELATED TO** COMMERCIALIZATION OF OUR ~~PRODUCT~~ **PRODUCTSOur** ~~AND PRODUCT CANDIDATESOur~~ ability to achieve profitability is highly dependent on the commercial success of Mydcombi and clobetasol propionate, and to the extent Mydcombi and clobetasol propionate are not successful, our business, financial condition and results of operations may be materially adversely affected and the price of

our common stock may decline. Mydcombi and clobetasol propionate are currently our only products that have been approved by FDA for commercial sale in the ~~U. S~~ **United States, and our prospects are substantially dependent on our and our licensees' abilities to successfully commercialize Mydcombi** . For the year ended December 31, ~~2023~~ **2024** , we recorded net sales of ~~Mydcombi of~~ $ ~~3~~ **57** , ~~787~~ **336** . Revenues from sales of Mydcombi **, clobetasol propionate and other products through our distribution and co- promotion agreements,** have not been sufficient to fund our operations fully in prior periods and we cannot provide assurance that revenues from ~~Mydcombi~~ **product** sales will be sufficient to fund our operations fully in the future. We will need to generate substantially more product revenue ~~from Mydcombi and / or clobetasol propionate generate other revenue such as through sales of future approved products~~ to achieve and sustain profitability. We may be unable to sustain or increase revenues generated from ~~Mydcombi~~ product sales for a number of reasons, including: ● pricing, coverage and reimbursement policies of government and private payers such as Medicare, Medicaid, the U. S. Department of Veterans Affairs, group purchasing organizations, insurance companies, health maintenance organizations and other plan administrators; ● a lack of acceptance by physicians, patients and other members of the healthcare community; ● interruptions in supply of Mydcombi from our contract manufacturing partners; ● the availability, relative price and efficacy of Mydcombi as compared to alternative treatment options or branded, compounded or generic competing products; ● an unknown safety risk; ● the failure to enter into and maintain acceptable partnering arrangements for marketing and distribution of Mydcombi outside of the **United States** ~~U. S.~~ ; and ● changed or increased regulatory restrictions in the **United States** ~~U. S.~~ , **European Union** ~~E. U.~~ and / or other foreign territories. ~~We~~ **44 In addition, we require substantial additional funding to advance manufacturing and commercialization of Mydcombi and development of the Gen- 2 Optejet. If additional capital is not available when needed, including because of general market conditions, we may need to significantly scale back or reprioritize our manufacturing and commercialization plans, and potentially even cease our operations. If we** are **unable** ~~dependent on our ability to successfully commercialize our product Mydcombi and clobetasol propionate, and our ability~~ to develop, obtain marketing approval for ~~and~~ **or** successfully commercialize **our** MicroPine ~~,~~ **and** MicroLine ~~, and any future product candidates. If we are unable to develop, obtain marketing approval for and / or successfully commercialize our products and~~ product candidates, either alone or through a collaboration, or experience significant delays in doing so, our business could be materially harmed. **Our** ~~Apart from Mydcombi and clobetasol propionate, we currently have no~~ products ~~approved for sale and have invested a significant portion of our efforts and financial resources in the development of MicroPine for pediatric progressive myopia and MicroLine for presbyopia. Our prospects are substantially dependent on our and our licensees abilities to develop, obtain marketing approval for and successfully commercialize Mydcombi and clobetasol propionate and these product candidates. The success of our product candidates will depend on, among other things, our ability to successfully complete clinical trials of each product candidate. Although we have completed multiple Phase II and III studies for our product candidates, including the MIST- 1 and MIST- 2 Phase III trials for Mydcombi, and the VISION- 1 and VISION- 2 Phase III trials for MicroLine, the clinical trial process is uncertain, and failure of one or more clinical trials can occur at any stage of testing. In addition to the successful completion of clinical trials, the success of our product candidates will also depend on several other factors, including the following: ● receipt of marketing approvals from the FDA or other applicable regulatory authorities; ● establishment of supply arrangements with third- party raw materials suppliers and manufacturers; 47 ● 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 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 contract research organizations,**

or CROs, and clinical trial sites; 48 ● obtaining sufficient quantities of our product candidates and other clinical trial material; or ● obtaining IRB approval to conduct a clinical trial at a prospective site. In addition, once a clinical trial has begun, it may experience unanticipated delays or be suspended or terminated by us, an IRB, the FDA or other regulatory authorities due to several factors, all of which could impact our, or our licensees', ability to complete clinical trials in a timely and cost- efficient manner, including: ● lack of adequate funding; ● failure to conduct the clinical trial in accordance with regulatory or IRB requirements; ● slower than expected rates of subject recruitment and enrollment; ● higher than anticipated participant drop-out rates; ● failure of clinical trial subjects to use the product as directed or to report data as per trial protocols; ● inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold; ● failure to achieve certain efficacy and / or safety standards; ● subjects experiencing severe side effects or other adverse events related to the investigational treatment; ● delayed or insufficient supply of clinical trial material or inadequate quality of such materials; ● failure of our CROs or other third- party contractors to meet their contractual obligations to us in a timely manner, or at all; or ● delays in quality control / quality assurance procedures necessary for study database lock and analysis of unblinded data. Significant clinical trial delays also could jeopardize our ability to meet obligations under agreements under which we license our rights to our product candidates, allow other companies to bring competitive products to market before we do, shorten any period of market exclusivity we may otherwise have under our patent rights, and weaken our negotiating position in discussions with potential collaborators, any of which could impair our ability to successfully commercialize our product candidates, if ultimately approved. Any significant delays in commencement or completion of clinical trials of our product candidates, or the suspension or termination of a clinical trial, could materially harm our business, financial condition and results of operations. We or our licensees may experience delays or difficulties in the enrollment and / or retention of patients in clinical trials, which could delay or prevent our receipt of necessary regulatory approvals. Successful and timely completion of clinical trials will require that we or our licensees sponsoring trials for our product candidates enroll a sufficient number of subjects. Subject enrollment, which is an important factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population and competition for patients eligible for our clinical trials with competitors which may have ongoing clinical trials for product candidates that are under development to treat the same indications as one or more of our product candidates, or approved products for the conditions for which we are developing our product candidates. Trials may be subject to delays as a result of subject enrollment taking longer than anticipated or subject withdrawal. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities. We cannot predict 49how successful we or our licensees will be at enrolling subjects in future clinical trials. Subject enrollment is affected by other factors including: ● the severity and difficulty of diagnosing the disease under investigation; ● the eligibility and exclusion criteria for the trial in question; ● the size of the patient population and process for identifying patients; ● our ability to recruit clinical trial investigators with the appropriate competencies and experience; ● the design of the trial protocol; ● the perceived risks and benefits of the product candidate in the trial in relation to other available therapies, including any new products that may be approved for the indications we are investigating; ● the availability of competing commercially available therapies and other competing therapeutic candidates' clinical trials for the disease or condition under investigation; ● the willingness of patients to be enrolled in our clinical trials; ● the risk that subjects enrolled in clinical trials will drop out of our trials before completion; ● our ability to obtain and maintain clinical trial subject informed consents ● the efforts to facilitate timely enrollment in clinical trials; ● potential disruptions caused by geopolitical events such as the ongoing war between Russia and Ukraine or between Israel and Hamas; ● the patient referral practices of physicians; ● the ability to monitor subjects adequately during and after treatment; and ● the proximity and availability of clinical trial sites for prospective subjects. Inability to enroll a sufficient number of subjects for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in these clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Furthermore, we rely on 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 50be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could be material and could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly. Furthermore, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or therapeutic product, if any, and us in general. The information we choose to publicly disclose regarding a particular nonclinical study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise

regarding a particular therapeutic product, if any, product candidate or our business. If the preliminary, interim and topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition. The FDA or comparable foreign regulatory authorities may disagree with our regulatory plans and we may fail to obtain regulatory approval of our product candidates. Our clinical trial results may not support regulatory approval of our product candidates. The results of nonclinical studies and clinical trials may not be predictive of the results of later- stage clinical trials, and product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and initial clinical trials. In addition, our product candidates could fail to receive regulatory approval for many reasons, including the following: ● the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; ● the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval; ● we may be unable to demonstrate that our product candidates' risk- benefit ratios for their proposed indications are acceptable; ● the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; ● the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials; ● the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of an application for marketing authorization to FDA or comparable foreign regulatory authorities; ● the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, our own manufacturing facilities, or a third- party manufacturer' s facilities with which we contract for clinical and commercial supplies; and ● the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. Failure to obtain regulatory approval to market any of our product candidates would significantly harm our business, results of operations, and prospects. 51Our 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 , **which** and such side effects or other properties could result in significant negative consequences following any marketing approval of any of our product candidates . **If** Undesirable side effects caused by any of our product candidates could cause us, our licensing partners, if any, or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority. Results of the clinical trials could reveal a high and unacceptable severity and prevalence of side effects or risks associated with a product candidate' s use. In such an event, our trials could be suspended or terminated and the regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug- related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. Additionally, if undesirable side effects of our products are identified following marketing approval , a number of potentially significant negative consequences could result, including: ● marketing of such product may be suspended; ● a product recall or product withdrawal; ● regulatory authorities may withdraw or limit their approvals of such product or may require additional warnings on the label; ● the requirement to develop a REMS for each product or, if a strategy is already in place, to incorporate additional requirements under the REMS, or to develop a similar strategy as required by a comparable foreign regulatory authority; ● the requirement to conduct additional post- market studies; and ● being sued and held liable for harm caused to subjects or patients. Consequently, our reputation and business operations may suffer. In addition, adverse side effects caused by any therapeutics that may be similar in nature to our product **products** candidates could delay or prevent regulatory approval of our product candidates, limit the commercial profile of an approved label for our product candidates, or result in significant negative consequences for our product **products** candidates following marketing approval . Any of these events could prevent the achievement or maintaining of market acceptance of the particular product or product candidate, if approved, and could significantly harm our business, results of operations and prospects. We might not be able to develop any additional 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 other than Mydcombi and clobetasol propionate. 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 other than Mydcombi and clobetasol propionate 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. 52If the market opportunities for Mydcombi and clobetasol propionate and 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 commercializing our Mydcombi and clobetasol propionate products, and we have licensed commercialization rights to Mydcombi as well as MicroPinc and MicroLinc in Greater China (mainland China, Hong Kong, Macau and Taiwan) and South Korea to Arctic Vision (with Senju retaining such licensed rights in the rest of Asia). Our understanding of both the number of people who have needs for our products, as well as the subset of people who have the potential to benefit from our product and 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~~ **products** ~~or 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 Mydcombi and clobetasol propionate ~~and 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. There can be no assurance that Mydcombi and clobetasol propionate will achieve commercial success or market acceptance ~~and~~ , ~~even if we receive regulatory approval to market our product candidates, our product candidates might not gain market acceptance upon their commercial introduction, both of~~ which could prevent us from becoming profitable. We may have difficulties convincing the medical community, third- party payors and consumers to accept and use Mydcombi ~~,~~ **or** clobetasol propionate ~~and any of our product candidates that may be approved for commercialization in the future~~. Other factors that we believe will affect market acceptance of Mydcombi ~~,~~ **or** clobetasol propionate ~~and our product candidates, if approved,~~ include: **45** ● the timing of our receipt of any marketing approvals, the terms of any approvals and the countries in which approvals are obtained; ● safety, efficacy and ease of administration of Mydcombi ~~,~~ **or** clobetasol propionate ~~or our product candidates~~; ● the success of physician education programs; ● the availability of any government and third- party payor reimbursement; ● the pricing of Mydcombi ~~,~~ **or** clobetasol propionate ~~or 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 Mydcombi ~~,~~ **or** clobetasol propionate ~~or any product candidates that we may develop in the~~ future; and ● the prevalence and severity of any adverse effects. **We** ~~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. 53We~~ 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~~ **products** ~~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 **our** ~~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 Mydcombi ~~,~~ **and** clobetasol propionate ~~and the product candidates for which we may in the future 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. We ~~received FDA approval for our primary Mydcombi manufacturing facility in February 2024, which we believe will allow us to expand and continue to build our manufacturing operations. However, we~~ may encounter delays in the manufacturing process for Mydcombi that could delay the process of commercialization of the product, which could have a material negative effect on our revenues. In addition, failure to secure contracts with manufacturers, wholesalers, retailers, or specialty pharmacies could negatively impact the production and distribution of our ~~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 **prior** clinical trials or for loss or harm suffered by users of Mydcombi ~~,~~ **or** clobetasol propionate ~~or any of our drug products 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 **such** commercialized drug or other significant enforcement action such as limiting the indications for which any such drug may be used, or suspension or withdrawal of approval for any such drug. **46** ~~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. 54Product~~ -- **Product** liability lawsuits against us could divert our resources and could cause us to incur substantial liabilities and to limit commercialization of any products that we develop. We face an inherent risk of product liability exposure related to the use of

Mydcombi ~~,~~ **or** clobetasol propionate ~~and our product candidates that we develop in human clinical trials~~. 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 Mydcombi ~~,~~ **or** clobetasol propionate ~~or 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; **and** ● reduced time and attention of our management to pursue our business strategy ~~; and ● the inability to commercialize any future 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 commercialize Mydcombi and clobetasol propionate ~~and expand or undertake new our clinical trials for existing and future product candidates~~. Insurance coverage is increasingly expensive. We might not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. In the event that we are required to pay damages for any such claim, we may be forced to seek bankruptcy or to liquidate because our asset and revenue base may be insufficient to satisfy the payment of damages and any insurance that we have obtained or may obtain for product or clinical trial liability might not provide sufficient coverage against potential liabilities. We may not be able to successfully commercialize Mydcombi ~~,~~ **or** clobetasol propionate ~~and 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 Mydcombi ~~,~~ **or** clobetasol propionate ~~or 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. ~~55Coverage~~ -- **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~~ **and47** ● neither experimental nor investigational. We cannot be sure that reimbursement will be available for Mydcombi ~~,~~ **or** clobetasol propionate ~~or any product that we may commercialize in the future~~ and, if coverage and reimbursement are available, what the level of reimbursement will be. Our inability to promptly obtain coverage and adequate reimbursement rates from both government- funded and private payors for **our** ~~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~~ **our** ~~product~~ **products** ~~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, or CMS, the federal agency responsible for administering the Medicare program, revises the reimbursement amounts paid to health care providers, including the Medicare Physician Fee Schedule and Hospital Outpatient Prospective Payment System, which may result in reduced Medicare payments. We expect to experience pricing pressures in connection with the sale of ~~any of~~ our ~~product~~ **products** ~~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 **our** ~~any approved product~~ **products**. We cannot predict the likelihood, nature or extent of government

regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. If we, or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our ~~product~~ **products** ~~candidates~~ may lose any regulatory approval that **has** ~~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. ~~56~~RISKS ~~--~~ **RISKS** RELATED TO REGULATORY APPROVAL OF OUR ~~PRODUCT~~ **PRODUCTS** ~~CANDIDATES~~ AND OTHER LEGAL COMPLIANCE ~~MATTERSThe~~ **MATTERSWe** ~~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 MicroPine and MicroLine are promising, such data may be insufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional nonclinical studies or clinical trials for our products either prior to or after approval, or it may object to elements of our clinical development programs. This could result in substantial additional costs or delays in the development of our product candidates. Our product candidates could fail to receive regulatory approval for many reasons, including the following: ● the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; ● we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication; ● the results of our clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; ● the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials; ● we may be unable to demonstrate that a product candidate' s clinical and other benefits outweigh its safety risks; ● the FDA or comparable foreign regulatory authorities may fail to approve our manufacturing processes or facilities of third- party suppliers with which we contract for clinical and commercial supplies of our product candidates; and ● the approval policies or regulations of the FDA or comparable foreign authorities may significantly change in a manner rendering our clinical data insufficient for approval. Of the large number of product candidates developed by pharmaceutical manufacturers, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval and marketing authorization process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval and marketing authorization to market MicroPine, MicroLine, or any of our future product candidates, which would significantly harm our business, financial condition, results of operations and prospects. 57We 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 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. MicroPine and MicroLine may be considered drug / device combinations and the process for obtaining regulatory approval in the United States will require compliance with complex procedures because concordance between two centers of the FDA (CDRH and CDER) is necessary for approval of combination products. We anticipate that our product candidates in development, MicroPine and MicroLine, will be considered drug / device combination products because, like Mydcombi, they are also pre- filled or co- packaged ophthalmic drug dispenser products intended for use only with the Optejet dispenser. In October 2021, we received a CRL from the FDA, which in part informed us that pre- filled or co- packaged ophthalmic drug dispenser products like Mydcombi have been reclassified as drug- device combination products. If MicroPine or MicroLine are not also designated as drug- device combination products, or if either CDER or CDRH were to institute additional requirements

~~for the approval of MicroPine or MicroLine, we could be required to complete clinical studies with more patients and over longer periods of time than is currently anticipated. This would significantly increase the anticipated cost and timeline to completion of MicroPine or MicroLine' s development and require us to raise additional funds. The FDA may determine that the results of our completed clinical trials are not sufficiently robust or convincing and require additional clinical and / or nonclinical studies prior to approval of MicroPine or MicroLine. The impact of either a change in the lead FDA review center or the imposition of additional, currently unanticipated requirements for approval could be significant to us and have a material adverse effect on the prospects for developing MicroPine or MicroLine, as well as on our business and our financial condition. If we receive regulatory approval for any of our current or future product candidates, we will be~~ subject to ongoing regulatory obligations and continued regulatory review **of our products** , which may result in significant additional expense. Additionally, our ~~product~~ **products** ~~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. **The** ~~If the FDA or a comparable foreign regulatory authority approves any of our current or future product candidates, the~~ manufacturing processes, labeling, packaging, distribution, storage, advertising, promotion, import, export, recordkeeping, monitoring, and reporting of our ~~product~~ **products is** ~~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 ~~58unanticipated~~ -- **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: **48** ● restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls; ● revision to the labeling, including limitations on approved uses or the addition of additional warnings, contraindications or other safety information, including boxed warnings; ● mandated modification of promotional materials and labeling and the issuance of corrective information; ● imposition of a REMS, which may include distribution or use restrictions; ● requirements to conduct additional post- market clinical trials to assess the safety of the product; ● fines, warning letters or other regulatory enforcement action; ● refusal by the FDA to approve pending applications or supplements to approved applications filed by us; ● suspension, limitation, or withdrawal of marketing approvals; ● ~~suspension of any of our ongoing clinical trials; ●~~ product seizure or detention, or refusal to permit the import or export of products; ● consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; and ● injunctions or the imposition of civil or criminal penalties ~~;~~ **.** Any government investigation of alleged violations of law would be expected to require us to expend significant time and resources in response and could generate adverse publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to ~~develop and~~ commercialize our products and our value and operating results would be adversely affected. In addition, the FDA' s and other comparable foreign regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay **commercialization** ~~regulatory approval~~ of our ~~product~~ **products** ~~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. ~~If we obtain FDA approval for any of our current or future product candidates in the United States, and although~~ **Although** we have obtained FDA approval for Mydcombi ~~and clobetasol propionate~~ in the United States, we may never obtain approval for or commercialize Mydcombi ~~, clobetasol propionate~~ or any of our current or future product candidates in any other jurisdiction, which would limit our ability to realize their full market potential. In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country- by- country basis regarding safety and efficacy. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions. For example, approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. ~~59Drug~~ -- **Drug** product approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. In many jurisdictions, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Other than Mydcombi and clobetasol propionate in the United States, we do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and

maintain required **49** approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized. Regulatory approval by the FDA or comparable foreign regulatory authorities is limited to those specific indications and conditions for which approval has been granted, and we may be subject to substantial fines, criminal penalties, injunctions, or other enforcement actions if we are determined to be promoting the use of our products for unapproved or " off- label " uses, or in a manner inconsistent with the approved labeling, resulting in damage to our reputation and business. We must comply with requirements concerning advertising and promotion for Mydcombi ~~,~~ **and** clobetasol propionate ~~and any product candidates for which we obtain marketing approval in the future~~ . 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~~ **the** product is approved. If we are not able to obtain FDA or comparable foreign regulatory authority approval for desired uses or indications for our ~~current product~~ **products** ~~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 Mydcombi ~~,~~ **or** clobetasol propionate ~~or 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 Mydcombi or clobetasol propionate ~~or, for our product candidates, 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- ~~60label~~ -- **label** uses. In addition, False Claims Act lawsuits may expose manufacturers to follow- on claims by private payors based on fraudulent marketing practices. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid, or other federal and state healthcare programs. If we do not lawfully promote our approved products we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations, stock price and prospects. In the United States, the promotion of pharmaceutical products are subject to additional FDA requirements and restrictions on promotional statements. If the FDA determines that our promotional activities violate its regulations and policies pertaining to product promotion, it could request that we modify our promotional materials or subject us to regulatory or other enforcement actions, including issuance of warning letters or untitled letters, suspension or withdrawal of an approved product from the market, requests for recalls, payment of civil fines, disgorgement of money, imposition of operating restrictions, injunctions or criminal prosecution, and other enforcement actions. Similarly, industry codes in foreign jurisdictions may prohibit companies from engaging in certain promotional activities and regulatory agencies in various countries may enforce violations of such codes with civil penalties. If we become subject **50** to regulatory and enforcement actions our business, financial condition, results of operations, stock price and prospects will be materially harmed. Furthermore, the use of our products for indications other than those approved by the FDA or comparable foreign regulatory authorities may not effectively treat such conditions. Any such off- label use of our product candidates could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use our products for these uses for which they are not approved, which could lead to product liability suits that that might require significant financial and management resources and that could harm our reputation. Our relationships with customers, health care providers, physicians, prescribers, purchasers, third- party payors, charitable organizations and patients are subject to applicable anti- kickback, fraud and abuse and other health care laws and regulations, which expose us to potential criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings. **We** ~~As a result of our~~

~~commercialization of Mydcombi, we~~ are ~~(and upon commercialization of our product candidates, will continue to be)~~ subject to ~~additional~~ **certain** health care statutory and regulatory requirements and oversight by federal and state governments in the United States as well as foreign governments in the jurisdictions in which we conduct our business. Health care providers, physicians and third- party payors in the United States and elsewhere play a primary role in the recommendation and prescription of biopharmaceutical products. Arrangements with third- party payors and customers can expose biopharmaceutical manufacturers to broadly applicable fraud and abuse and other health care laws and regulations, including, without limitation, the federal Anti- Kickback Statute ~~, or the AKS,~~ and the ~~FCA~~ **False Claims Act** , which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute biopharmaceutical products. In particular, the research of our product candidates, as well as the promotion, sales and marketing of health care items and services, as well as certain business arrangements in the health care industry, are subject to extensive laws designed to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission (s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The health care laws that may affect us include: the federal fraud and abuse laws, including the ~~AKS~~ **federal Anti- Kickback Statute** ; false claims and civil monetary penalties laws, including the False Claims Act and Civil Monetary Penalties Law; federal data privacy and security laws, including HIPAA, as amended by HITECH; and the federal Physician Payments Sunshine Act which requires us to report to CMS annually any transfers of value made to physicians (defined broadly to include doctors, dentists, optometrists, podiatrists, chiropractors, and other advanced practice health care professionals), certain non- physician health care practitioners and teaching hospitals as well as ownership and investment interests held by physicians and their immediate family members. In addition, many states have similar laws and regulations that may differ from each other and federal law in significant ways, thus complicating compliance efforts. Moreover, several states require biopharmaceutical companies to comply with the biopharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require manufacturers to report information related to payments and other transfers of value to physicians and other health care providers or marketing expenditures. Additionally, some state and local laws require the registration of biopharmaceutical sales representatives in the jurisdiction. ~~61The~~ -- **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 **51** 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, or HHS, as of January 1, 2022, as well as several changes to the statutes governing FDA' s drug and biologic programs. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and as a result, certain sections of the ACA have not been fully implemented or have been effectively repealed through Executive Orders and / or executive agency actions. However, following several years of litigation in the federal courts, in June 2021, the U. S. Supreme Court upheld the ACA when it dismissed a legal challenge to the ACA' s constitutionality. Further legislative and regulatory changes under the ACA remain possible, but it is unknown what form any such changes or any law would take, and how or whether it may affect the biopharmaceutical industry as a whole or our business in the future. We expect that changes or additions to the ACA, the Medicare and Medicaid programs, such as changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the health care industry in the United States. Further, over the past several years there has been heightened governmental scrutiny over the manner in which biopharmaceutical manufacturers set prices for their marketed products, which has resulted in several U. S. Congressional inquiries and proposed

and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. The probability of success of these newly announced policies, many of which have been subjected to legal challenge in the federal court system, and their potential impact on the U. S. prescription drug marketplace is unknown. There are likely to be continued political and legal challenges associated with implementing these reforms as they are currently envisioned. For example, in July 2021, President Biden issued a sweeping executive order on promoting competition in the American economy that includes several mandates pertaining to the pharmaceutical and health care insurance industries, and called on HHS to release a comprehensive plan to combat high prescription drug prices. The drug pricing plan released by HHS in September 2021 in response to the executive order makes clear that the Biden Administration supports aggressive action to address rising drug prices, including allowing HHS to negotiate the cost of Medicare Part B and D drugs, but such significant changes will require either new legislation to be passed by Congress or time- consuming administrative actions. Accordingly, there remains a large amount of uncertainty regarding the federal government' s approach to making pharmaceutical treatment costs more affordable for patients. ~~62In~~ **In** August 2022, President Biden signed into the law the Inflation Reduction Act of 2022 **(** ~~, or~~ the **"** IRA **")** . Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. Starting in 2023, a manufacturer of a drug or biological product covered by Medicare Parts B or D must pay a rebate to the federal government if the product' s price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting in payment year 2026, CMS will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. The effect of the Inflation Reduction Act of 2022 on our business and the healthcare industry in general is not yet known. There remains a large amount of uncertainty regarding the federal government' s approach to making pharmaceutical treatment costs more affordable for patients. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, California requires pharmaceutical manufacturers to notify certain purchasers, including health insurers and government health plans at least 60 days before any scheduled increase in the wholesale acquisition cost ~~, or~~ **(" ")** , 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 **52** 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~~ **(" ")** , and other members of the healthcare and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area. The Federal Trade Commission in mid- 2022 also launched sweeping investigations into the practices of the PBM industry that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. Significant efforts to change the PBM industry as it currently exists in the United States may affect the entire pharmaceutical supply chain and the business of other stakeholders, including biopharmaceutical developers like us. Legally mandated price controls on payment amounts by third- party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action. We expect that additional federal and state health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures. We are subject to anti- corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, be precluded from developing manufacturing and selling products outside the United States or be required to develop and implement costly compliance programs, which could adversely affect our business, results of operations and financial condition. 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~~ **(" ")** , and the United Kingdom Bribery Act 2010 ~~, or~~ **(" ")** , 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 ~~63business~~ -- **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 **53** of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs. We might not be completely effective in ensuring our compliance with all applicable Anti- Corruption Laws or other legal requirements, including Trade Control laws. If we are not in compliance with Anti- Corruption Laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. The SEC also may suspend or bar issuers from trading securities on United States exchanges for violations of the FCPA' s accounting provisions. Any investigation of any potential violations of Anti- Corruption Laws or Trade Control laws by U. K., **United States** ~~U. S.~~ or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition. Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. The coronavirus pandemic has also adversely affected the operations of necessary government agencies. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. In addition, competing demands from other companies or issues can affect the timeliness for which the FDA can review and process our regulatory submissions. ~~64RISKS~~ -- **RISKS** RELATED TO OUR BUSINESS OPERATIONS AND MANAGING GROWTHWe are highly dependent on the services of our senior management team, including our Chief Executive Officer, and if we are not able to retain these members of our management team or recruit and retain additional management, clinical, scientific and sales personnel, our business will be harmed. We are highly dependent on our senior management team, including our Chief Executive Officer. The employment agreements we have with our executive officers do not prevent such persons from terminating their employment with us at any time. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives. In addition, we are dependent on our continued ability to ~~attract,~~ retain and motivate highly qualified additional ~~management, clinical, scientific, and sales~~ personnel. If we are not able to retain our management and to **retain** ~~attract, on acceptable terms, additional qualified~~ personnel necessary for the ~~continued development of our business and~~ commercialization of our ~~product~~ **products** ~~candidates~~, we might not be able to sustain our operations or grow. We might not be able to ~~attract or~~ retain qualified personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Many of the other medical technology companies that we compete against for qualified personnel and consultants have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high- quality

candidates and consultants than what we have to offer. If we are unable to continue to ~~attract,~~ retain and motivate high- quality personnel and consultants to accomplish our business objectives, ~~the rate and success at which we can discover and develop drug candidates and~~ our business will be limited ~~and we may experience constraints on our development objectives~~ . **54** ~~Our future performance will also depend, in part, on our ability to successfully integrate newly hired executive officers into our management team and our ability to develop an effective working relationship among senior management.~~ We have limited corporate infrastructure ~~and may experience difficulties in managing growth~~ . As of March 15, ~~2024~~ **2025** , we had ~~only 57~~ **14 total employees. Thirteen are** full **-** time employees **and one is part- time** and we rely on third- party contractors for the provision of professional and other services. ~~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~~ -- **the** ~~growth activities~~ **exploration of our strategic alternatives** . We might not be able to effectively manage ~~the expansion of~~ our **day- to- day** operations, which may result in weaknesses in our infrastructure, operational inefficiencies, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our ~~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 successfully commercialize Mydcombi ~~,~~ **and** clobetasol propionate ~~and our drug candidates~~ , ~~develop a scalable infrastructure~~ and ~~compete effectively~~ **our ability to find a suitable strategic transaction** will depend, in part, on our ability to effectively ~~manage any future growth~~ **utilize our corporate infrastructure** . We rely upon information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security incidents, could harm our ability to operate our business effectively. In the ordinary course of our business, we collect and store sensitive data and intellectual property and proprietary business information owned or controlled by ourselves or our customers. This data encompasses a wide variety of business- critical information including research and development information, operational information, commercial information, and business and financial information. We face four primary risks relative to protecting this critical information: loss of access; inappropriate disclosure; inappropriate modification; and inadequate monitoring of our controls over the first three risks. The secure processing, storage, maintenance, and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses, breaches, interruptions due to employee error, malfeasance, faulty password management, lapses in compliance with privacy and ~~65security~~ -- **security** mandates, or other disruptions. The risk of a security breach or disruption, particularly through cyber- attack or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Our IT networks and related systems are essential to the operation of our business and our ability to perform day- to- day operations. ~~. 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 **substantial** liability ~~and further development of our product candidates could be delayed~~ . Although we make efforts to maintain the security and integrity of these types of IT networks and related systems, and we have implemented various measures to manage the risk of a security breach or disruption, there can be no assurance that our security efforts and measures will be effective or that attempted security breaches or disruptions would not be successful or damaging. Our information technology systems may have vulnerabilities, and we may not have the resources or technical sophistication to anticipate or prevent rapidly evolving types of cyberattacks, such as ransomware attacks. A significant cyber incident, including system failure, security breach, disruption by malware or other damage, could interrupt or delay our operations, result in a violation of applicable cybersecurity and privacy and other laws, damage our reputation, cause a loss of customers or expose sensitive customer data, or give rise to monetary fines and other penalties, which could be significant. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost, or stolen. Third parties may attempt to fraudulently induce employees or other persons into disclosing usernames, passwords or other sensitive information, which may in turn be used to access our information systems, commit identity theft or carry out other unauthorized or illegal activities. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. We engage third- party vendors and service providers to store and otherwise process some of our data, including sensitive and personal information. Our vendors and service providers may also be the targets of the risks described above, including cyberattacks, malicious software, phishing schemes, and fraud. Our ability to monitor our vendors and service providers' data security is limited, and, in any event, third parties may be able to circumvent those security measures, resulting in the unauthorized access to, misuse, disclosure, loss or destruction of our data, including sensitive and personal information, and disruption of our or third- party service providers' systems. We and our third- party service providers may face difficulties in identifying, or promptly responding to, potential security breaches and other instances of unauthorized access to, or disclosure or other loss of, information. Any hacking or other attack on our or our third- party service providers' or vendors' systems, and any unauthorized access to, or disclosure or other loss of, information suffered by us or our third- party service providers or vendors, or the perception that any of these have occurred, could result in legal claims or proceedings, loss of intellectual property, liability under laws that protect the privacy of personal information, negative publicity, disruption of our operations and damage to our reputation, which could divert our management' s attention from the operation of our business and materially and

adversely affect our business, revenues and competitive position. Moreover, we may need to increase our efforts to train our personnel to detect and defend against cyber- or phishing- attacks, which are becoming more sophisticated and frequent, and we may need to implement additional protective measures to reduce the risk of potential security breaches, which could cause us to incur significant additional expenses. **55** Any such security breach or interruption, as well as any action by us or our employees or contractors that might be inconsistent with the rapidly evolving data privacy and security laws and regulations applicable within the United States and elsewhere where we conduct business, could result in enforcement actions by U. S. states, the U. S. federal government or foreign governments, liability or sanctions under data privacy laws that protect personally identifiable information, regulatory penalties, other legal proceedings such as but not limited to private litigation, the incurrence of significant remediation costs, disruptions to our development programs, business operations and collaborations, diversion of management efforts and damage to our reputation, which could harm our business and operations. Because of the rapidly moving nature of technology and the increasing sophistication of cybersecurity threats, our measures to prevent, respond to and minimize such risks may be unsuccessful. In addition, our insurance may be insufficient to cover our losses resulting from cyber- attacks, breaches, or other interruptions, and any incidents may result in loss of, or increased costs of, such insurance. The successful assertion of one or more large claims against us that exceed available insurance coverage, the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co- insurance requirements, or denials of coverage, could have a material adverse effect on our business, including our financial condition, results of operations and reputation. ~~66Our~~ -- **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 PARTIESWe ~~rely on third parties to conduct, supervise, and monitor our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects. We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. As a result, we are and expect to remain dependent on third parties to conduct our current and future preclinical studies and clinical trials. CROs that manage our preclinical studies and clinical trials as well as clinical investigators, including in investigator- initiated clinical trials, and consultants play a significant role in the conduct of our preclinical studies and clinical trials and the subsequent collection and analysis of data. The timing of the initiation and completion of these studies and trials will therefore be partially controlled by such third parties and may result in delays to our development programs. Nevertheless, we are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal requirements, and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GLP and GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GLP and GCP requirements through periodic inspections of preclinical study sites, trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs or clinical trial sites, including clinical trial sites in investigator- initiated clinical trials, fail to comply with applicable GLP or GCP requirements, the data generated in our preclinical studies and clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional preclinical or clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to stop and / or repeat clinical trials, which would delay the marketing approval process. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government- sponsored database, clinicaltrials. gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. If any of these third parties fails to meet expected deadlines, adhere to our clinical protocols or comply with applicable regulatory requirements, otherwise performs in a substandard manner, or terminates its engagement with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If any of~~

~~our clinical trial sites terminates for any reason, we may experience the loss of follow- up information on subjects enrolled in such clinical trials unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible. In addition, clinical trial investigators for our clinical trials or investigator- initiated clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts 67of 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~~ may encounter delays in the manufacturing of the second generation Optejet device, including as a result of our reliance on third parties for manufacturing activities, and this may cause delays in the commercialization of our products ~~and our product candidatess~~. Any such delays would increase the risk that we will not have sufficient quantities of our ~~product~~ **products** ~~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 commercial production of Mydcombi. If we are unable to establish adequate manufacturing processes internally or to reach and maintain agreements with third parties to help us with manufacturing, our commercialization activities would be delayed. Reliance on third- party providers may expose us to more risk than if we were to manufacture our ~~product~~ **products** ~~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~~ **products** ~~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 Mydcombi. We may be unable to conclude agreements for commercial supply with a sufficient number of suppliers or may be unable **56** to do so on acceptable terms. If we are unable to reach acceptable agreements with a sufficient number of suppliers of materials, our commercialization activities will be delayed and our ability to implement our business plan will be compromised. Our manufacturing process is complicated and expensive and it requires months of advance planning. We rely on a limited number of manufacturers for our current supply of Mydcombi for commercialization. If we were unable to acquire the necessary amount of deliverables to meet market demand, our ability to commercialize ~~could be delayed substantially. Additionally, 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 68or 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 Mydcombi in sufficient quantities for commercialization ~~or to meet an increase in demand, or, for our unapproved clinical products, our clinical trials,~~ as a result of capacity constraints or delays or disruptions in the market for the raw materials or active pharmaceutical ingredients, including shortages caused by the purchase of such raw materials or active pharmaceutical ingredients by our competitors or others. The failure by us or our third- party suppliers to obtain the raw materials or active pharmaceutical ingredients necessary to manufacture sufficient quantities of Mydcombi ~~and 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. Our third- party suppliers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. Our failure, or the failure of our third- party suppliers, to comply with applicable regulations could result in regulatory actions, such as the issuance of FDA Form 483 notices of observations, warning letters or sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of Mydcombi ~~and 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 Mydcombi ~~and our product candidates~~ could suffer significant interruptions. ~~69Any~~ -- **Any** disruption, such as a fire, natural hazards or vandalism at our third- party suppliers could significantly interrupt our manufacturing capability. We currently do not have alternative production plans in place or disaster- recovery facilities available. In case of a disruption, we will have to establish alternative component supply sources. This would require substantial capital on our part, which we may not be able to obtain on commercially acceptable terms or at all. Additionally, we would likely experience months of manufacturing delays as we build facilities or locate alternative suppliers and seek and obtain necessary regulatory approvals. If this occurs, we will be unable to satisfy manufacturing needs on a timely basis, if at all. If changes to third- party suppliers occur, then there also may be changes to manufacturing processes inherent in the setup of new operations for our ~~product candidates and any~~ products ~~that may obtain approval in the future~~. Any such changes could require the conduct of bridging studies before we can use any materials produced at new facilities ~~or under new processes in clinical trials or, for any products reaching approval,~~ in our commercial supply. Further, business interruption insurance may not adequately compensate us for any losses that may occur and we would have to bear the additional cost of any disruption, such as loss of potential sales of Mydcombi. For these reasons, a significant disruptive event of any third- party suppliers could have drastic consequences, including placing our financial stability at risk. Mydcombi ~~,~~ **and** clobetasol propionate ~~and our product candidates and any drugs that we may develop~~ may compete with other product candidates and drugs for access to manufacturing facilities. There are no assurances we would be able to enter into similar commercial arrangements with other manufacturers that operate under cGMP regulations and other applicable regulatory requirements and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future suppliers could delay clinical development or marketing approval. If we were to experience an unexpected loss of supply of or if any supplier were unable to meet our clinical or commercial demand for Mydcombi ~~,~~ **or** clobetasol propionate ~~or 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 commercialization of Mydcombi ~~,~~ **and** clobetasol propionate ~~and any other product candidates that reach approval, and our clinical trials~~, which would materially adversely affect our business, financial condition and results of operation. **57** If we, our service providers or our third- party manufacturers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business. If we, our service providers, or any third- party manufacturers fail to comply with laws regulating the protection of the environment and health and human safety, we could be subject to enforcement actions and our business prospects could be adversely affected. Our commercialization ~~and 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. ~~70If~~ **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~~ **products** ~~candidates~~ successfully and could harm our reputation and lead to reduced acceptance of our ~~product~~ **products** ~~candidates~~. These enforcement actions may include: ● restrictions on, or prohibitions against, marketing our products ~~or our product candidates~~; ● restrictions on importation of our products ~~or 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 LITIGATIONOur 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~~ **products** ~~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 **or have had** access to confidential or patentable aspects of our research and development output, such as our employees, contractors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights may be uncertain. Our pending and future patent applications might not result in patents being issued which protect our technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if our patent applications issue as patents, they might not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. In addition, changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, **58** 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. ~~71Some~~ -- **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~~ **products** ~~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~~ **products** ~~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. **59** ~~72The~~ -- **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~~ **products** ~~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~~ **products** ~~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 ~~73future~~ -- **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. **60** 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~~ **products** ~~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 74before 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. **61** patent system from a " first to invent " system to a " first inventor to file " system, expanding the definition of prior art, and developing a post- grant review system. This legislation changed U. S. patent law in a way that may weaken our ability to obtain patent protection in the United States for those applications filed after March 16, 2013. Further, the America Invents Act created new procedures to challenge the validity of issued patents in the United States, including post- grant review and inter partes review proceedings, which some third parties have been using to cause the cancellation of selected or all claims of issued patents of competitors. For a patent with an effective filing date of March 16, 2013 or later, a petition for post- grant review can be filed by a third party in a nine- month window from issuance of the patent. A petition for inter partes review can be filed immediately following the issuance of a patent if the patent has an effective filing date prior to March 16, 2013. A petition for inter partes review can be filed after the

nine- month period for filing a post- grant review petition has expired for a patent with an effective filing date of March 16, 2013 or later. Post- grant review proceedings can be brought on any ground of invalidity, whereas inter partes review proceedings can only raise an invalidity challenge based on published prior art and patents. These adversarial actions at the USPTO review patent claims without the presumption of validity afforded to U. S. patents in lawsuits in U. S. federal courts, and use a lower burden of proof than used in litigation in U. S. federal courts. Therefore, it is generally considered easier for a competitor or third party to have a U. S. patent invalidated in a USPTO post- grant review or inter partes review proceeding than invalidated in a litigation in a U. S. federal court. If any of our patents are challenged by a third party in such a USPTO proceeding, there is no guarantee that we, our licensors or collaborators will be successful in defending the patent, which would result in a loss of the challenged patent right to us. In addition, court rulings in cases such as Association for Molecular Pathology v. Myriad Genetics, Inc., BRCA1- & BRCA2- Based Hereditary Cancer Test Patent Litigation, Promega Corp. v. Life Technologies Corp. and Abbvie Deutschland GmbH v. Janssen Biotech, Inc. have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on future actions by the U. S. Congress, the U. S. courts, the USPTO and the relevant law- making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Any changes to patent law in the United States or other jurisdictions that impairs our ability to protect our ~~product~~ **products** ~~candidates~~ could have a material adverse effect on our business, financial condition, results of operations, and prospects. ~~75We~~ **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 **62** 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~~ **products** ~~candidates~~. Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our ~~product~~ **products** ~~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~~ **products** ~~candidates or approach to complement inhibition~~. If any third- party patents or patent applications are found to cover our ~~product~~ **products** ~~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~~ **products** ~~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~~ **products** ~~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~~ **products** ~~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~~ **products** ~~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~~ **products** ~~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 ~~76or~~ **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~~ **products** ~~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, **63** 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. ~~77We~~ **We** may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful. Competitors may infringe, misappropriate, or otherwise violate our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent' s claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving one or more of our patents could limit our ability to assert those patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the

marks in question. In this case, we could ultimately be forced to cease use of such trademarks. Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which might not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could adversely affect the price of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Any such litigation could have a material adverse effect on our business, financial condition, results of operations, and prospects. If we fail to comply with our obligations under our existing and any future intellectual property licenses with third parties, we could lose license rights that are important to our business. We may be reliant upon licenses to certain patent rights and proprietary technology form third parties that are important or necessary to the ~~development~~ **commercialization** of our product candidates. These and other licenses might not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to ~~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. **64** 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 ~~78interpretation --~~ **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~~ **products** ~~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~~ **products** ~~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~~ **products** ~~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 **65** 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 ~~79be~~ **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 STOCKA 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 ~~15~~ **31** , ~~2024~~ **2025** , we had ~~47~~ **300** , ~~386~~ **000** , ~~349~~ **000 shares of common stock authorized and 2, 830, 546** shares of common stock outstanding, ~~10~~ **1** , ~~926~~ **363** , ~~554~~ **135** shares of common stock issuable upon exercise of warrants, ~~6~~ **56** , **318** ~~154, 595~~ shares of our common stock issuable upon exercise of options, ~~2~~ **5** , ~~327~~ **952** , ~~747~~ **380** of shares issuable upon the conversion of convertible debt **and 247** , **623** ~~241, 764~~ shares of common stock issuable upon the vesting and / or delivery of restricted stock units ~~and $ 3. 0 million in shares of common stock issuable to Bausch Health Companies Inc. upon achievement of certain regulatory milestones~~ . 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 ~~2023~~ **2024** . As a result of this volatility, you might not be able to sell your common stock at or above the price at which you purchase it. From ~~our IPO in~~ January ~~2018~~ **1, 2020** through March 15, ~~2024~~ **2025** ~~,~~ the per share trading price of our common stock has been as high as $ ~~10~~ **617** . ~~74~~ **60** and as low as $ 1. ~~05~~ **43** . The per share trading price of our common stock might continue to fluctuate significantly in response to various factors, some of which are beyond our control. These factors include: ● general economic, industry and market conditions, including as a result of the coronavirus pandemic and geopolitical events such as the ongoing war between Russia and Ukraine or between Israel and Hamas; ● our ability to successfully manufacture and commercialize Mydcombi and clobetasol propionate; ● ~~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; 80 ●~~ actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts; **66** ● 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; **● amount of our debt servicing; ● the progress and outcome of our search for strategic alternatives;** and ● the other factors described in this " Risk Factors " section. We have broad discretion in the use of our cash, including the net proceeds from our financings, and might not use them effectively. Our management will have broad discretion in the application of our cash, including the net proceeds from our financing transactions, and could spend our cash in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest our cash, including the net proceeds from our financings, in a manner that does not produce income or that loses value. ~~Our~~ **We may be adversely affected by the effects of inflation. Inflation has the potential to adversely affect our liquidity,** business ~~is subject to changing regulations regarding corporate governance~~ , **financial condition** and results of operations by increasing our overall cost structure.The existence of inflation in the economy has resulted in,and may continue to result in,higher interest rates ~~81and~~ -- **and** capital costs,shipping costs,supply shortages,increased costs of labor,weakening exchange rates and other similar effects.Recently,inflation has increased throughout the U.S.economy ~~.Inflation can adversely affect us by increasing the costs of clinical trials and research,the development of our product candidates,administration and other costs of doing business~~

.We may experience increases in the prices of labor and other costs of doing business.In an inflationary environment,cost increases may outpace our expectations,causing us to use our cash and other liquid assets faster than forecasted.If this happens,we may need to raise additional capital to fund our operations,which may not be available in **sufficient amounts or on reasonable terms,if at all,sooner than expected.As a public company,we need to have effective internal controls and** disclosure controls, ~~internal control over~~ **which is costly and time consuming. Failure to develop and maintain adequate** financial ~~reporting~~ **controls could cause us to have material weaknesses** , **which could adversely affect** ~~and other compliance areas that will increase both~~ our ~~costs~~ **operations** and **financial position** ~~the risk of noncompliance~~ . As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes- Oxley Act of 2002, or the Sarbanes- Oxley Act, the Dodd- Frank Act, and the rules and regulations of our stock exchange. The requirements of these rules and regulations will increase our legal, accounting, and financial compliance costs, will make some activities more difficult, time- consuming, and costly, and may also place undue strain on our personnel, systems, and resources ~~. The Sarbanes- Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. Commencing with our fiscal year ending December 31, 2018, we performed system and process evaluation and testing of our internal control over financial reporting so that management could report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes- Oxley Act. Our compliance with Section 404 of the Sarbanes- Oxley Act requires that we incur substantial accounting expense and expend significant management efforts. Prior to our IPO, we had never been required to test our internal controls within a specified period~~ . We are required to disclose changes made to our internal control and procedures on a quarterly basis. However, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes- Oxley Act until we are no longer a " smaller reporting company " as defined in the rules of the SEC. If we are not able to comply with the requirements of Section 404 of the Sarbanes- Oxley Act in a timely manner, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC, or other regulatory authorities, which would require additional financial and management resources. We may be adversely affected by the..... 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 **67** and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC, or other regulatory authorities. Any failure to develop or maintain effective controls, or any difficulties encountered in their implementation or improvement, could harm our operating results or cause us to fail to meet our reporting obligations. Any failure to implement and maintain effective internal controls also could adversely affect the results of periodic management evaluations regarding the effectiveness of our internal control over financial reporting that we are required to include in our periodic reports filed with the SEC under Section 404 of the Sarbanes- Oxley Act. Ineffective disclosure controls and procedures or internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the trading price of our common stock. Implementing any appropriate changes to our internal controls may require specific compliance training of our directors, officers, and employees, entail substantial costs in order to modify our existing accounting systems, and take a significant period of time to complete. Such changes may not be effective, however, in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and could materially impair our ability to operate our business. In the event that we are not able to demonstrate compliance with Section 404 of the Sarbanes- Oxley Act in a timely manner, that our internal controls are perceived as inadequate, or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and our stock price could decline. We are an " smaller reporting company " and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors. We are considered a " smaller reporting company " under Rule 12b- 2 of the Exchange Act. We are therefore entitled to rely on certain reduced disclosure requirements, such as an exemption from providing selected financial data and executive compensation information. These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company also mean our auditors are not required to review our internal control over financial reporting and may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our common stock prices may be more volatile. We will remain a smaller reporting company until our public float exceeds $ 250 million as of the last business day of our most recently completed second quarter if our annual revenues are $ 100 million or more as of our most recently completed fiscal year, or until our public float exceeds $ 700 million as of the last business day of our most recently completed second quarter if our annual revenues are less than $ 100 million as of our most recently completed fiscal year. Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our certificate of incorporation, and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our Board of Directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove ~~82our~~ -- **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~~ **and68** ● 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. ~~83~~ **If securities analysts do not continue to publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline. The trading market for our common stock will rely, in part, on the research and reports that industry or financial analysts publish about us or our business. If securities analysts do not continue coverage of us, the trading price of our stock could decrease. Additionally, if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline. The accuracy of our financial reporting depends on the effectiveness of our internal control over financial reporting. We have identified material weaknesses in our internal control over financial reporting, which may raise questions regarding the accuracy and reliability of our financial statements and our ability to report accurately in the future. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis. During the process of preparing the financial statements as of and for the year ended December 31, 2024, we determined that we had material weaknesses related to the incorrect valuation of the Company' s accounting for shares of common stock that were issued for licensing agreements and debt modification and the impairment of a right- of- use asset. Due to the existence of these material weaknesses, our management has concluded that as of December 31, 2024, our internal control over financial reporting was not effective. 69**