

Risk Factors Comparison 2024-03-08 to 2023-03-31 Form: 10-K

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Investing in our common stock involves risk. You should carefully consider the risks described below as well as all the other information in this Annual Report on Form 10-K, including the consolidated financial statements and the related notes included in this report. The risks and uncertainties described below are not the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. If any of the following risks actually occur, our business, results of operations and financial condition could suffer. In that event, the trading price of our common stock could decline, and you may lose all or part of your investment. The risks discussed below also include forward- looking statements, and our actual results may differ substantially from those discussed in these forward- looking statements.

SUMMARY OF PRINCIPAL RISK FACTORS We face risks from: • our dependence on the commercial success of our ~~only product~~ **products**, **ILUVIEN and YUTIQ**; • the competition we face, given that the number of competitive products is growing and our competitors include larger, more established, fully integrated pharmaceutical companies and biotechnology companies that have substantially greater capital resources, existing competitive products, larger research and development staffs and facilities, greater marketing capabilities, and greater experience in drug development and in obtaining regulatory approvals than we do; • uncertainty associated with our ability to retain our current employees and to recruit and retain the new employees we need in the future, in particular a productive sales force; • the possibility that the NEW DAY Study may (a) fail to demonstrate the efficacy of ILUVIEN as baseline therapy in patients with early ~~diabetic macular edema (DME)~~ or to generate data demonstrating the benefits of ILUVIEN when compared to the current leading therapy for DME, and (b) take longer or be more costly to complete than we currently anticipate; • our inability to expand our portfolio of ophthalmic products; • the negative effects of inflation, which may increase the compensation we must pay to retain and attract a high- quality workforce and is likely to increase our operational costs; • our dependence on **single-sourced** third- party manufacturers to manufacture ~~ILUVIEN our products~~ or any future products or product candidates in sufficient quantities and quality, in a timely manner (~~particularly during the COVID-19 pandemic~~), and at an acceptable price; • the possibility that we may fail to plan appropriately to meet the demand of our customers for **ILUVIEN our products**, which could lead either to (a) **ILUVIEN our products** being out of stock or (b) our investment of a greater amount of cash in inventory than we need; • the possibility that the issues affecting global supply chains may negatively impact our ability to source materials and components to make ~~ILUVIEN our products~~ or to deliver ~~ILUVIEN our products~~ into our current markets; • uncertainty associated with manufacturing components and materials being superseded or becoming obsolete; • the possibility that we may ~~again~~ fail to comply with the financial covenants in our credit facility, and in that event be unable to obtain a waiver for any resulting default; • ~~our~~ **the possibility we** need to raise additional financing, the terms of which may restrict our operations and, if the capital we raise is equity or a debt security that is convertible into equity, could dilute our stockholders' investment; • uncertainty regarding our ability to achieve profitability and positive cash flow through the commercialization of ILUVIEN in the U. S., the ~~European Economic Area (EEA)~~ and other regions of the world where we sell ILUVIEN; • **uncertainty regarding our ability to achieve profitability and positive cash flow through the commercialization of YUTIQ in the U. S. to treat chronic NIU- PS**; • a slowdown or reduction in our sales due to, among other things, a reduction in end user demand, unexpected competition, regulatory issues or other unexpected circumstances, ~~including COVID-19~~; • the effects of inflation on the SOFR- based interest rate we pay under our credit facility, which could cause our financing costs to increase materially and thus adversely affect our financial results; • the possible continued delays in enrollment of patients in our ~~NEW DAY Study~~ **current or future studies**; • the possible delay in enrollment of patients in our pediatric study for ~~non- infectious uveitis affecting the posterior segment of the eye (NIU- PS)~~; • uncertainty associated with our pursuit of reimbursement from local health authorities in certain countries for the recently obtained additional indication for ILUVIEN for NIU- PS; • delay in or failure to obtain regulatory and reimbursement of ILUVIEN **and YUTIQ** or any future products or product candidates in additional markets where we do not currently sell ILUVIEN **and YUTIQ**; • uncertainty associated with our ability to meet any post market requirements for NIU- PS in the EEA; • the possibility that we may fail to secure regulatory approval in the greater China market, which would have an adverse effect on our ability to receive milestone payments under the Ocumension license agreement; • uncertainty associated with our ability to successfully commercialize ILUVIEN **and YUTIQ** following regulatory approval in additional markets; • ~~political, economic, legal and social risks, including those related to the COVID-19 pandemic~~; and • the possibility that we may be adversely affected by the expiration of patents that protect key aspects of ~~ILUVIEN our products~~ in the near- to medium- term.

~~15Risks-16Risks~~ **Risks Related to Our Business** ~~Our Business~~ **Our**, ~~Including Our Dependence on~~ **ILUVIEN** Our business depends on our ~~only product~~ **products**, **ILUVIEN and YUTIQ**. We are a pharmaceutical company with ~~two only one product~~ **products**, **ILUVIEN**, currently available for commercial sale in the U. S., the U. K., most of the countries in the EEA and a limited number of other markets, **and our other product, YUTIQ, available for commercial sale in the U. S.** Because we do not currently have any other products or product candidates available for sale or in clinical development, our future success depends on our and our distributors' successful commercialization of ILUVIEN **and YUTIQ**. **We market ILUVIEN directly in the U. S., Germany, the U. K., Portugal and Ireland. In addition, we have entered into various agreements under which distributors are providing or will provide regulatory, reimbursement and sales and marketing support for ILUVIEN in Austria, Belgium, the Czech Republic, Denmark, Finland, France, Italy, Luxembourg, the Netherlands, Norway, Spain, Sweden, Switzerland, Australia, New Zealand and several countries in the Middle East. In addition, we have granted an exclusive license to Ocumension for the development and**

commercialization of our 0.19 mg fluocinolone acetonide intravitreal injection in China, East Asia and the Western Pacific. As of December 31, 2023, we have recognized sales of ILUVIEN to international distributors in the Middle East, China, Austria, Belgium, Czech Republic, France, Italy, Luxembourg, Spain, the Netherlands, and certain Nordic countries. In the U. S., YUTIQ is indicated for the treatment and prevention of chronic NIU- PS. Pursuant to the Product Rights Agreement with EyePoint Parent, we have the commercialization rights to YUTIQ in the entire world, except Europe, the Middle East and Africa as we had previously licensed from EyePoint rights to certain products, which included YUTIQ (known as ILUVIEN in Europe, the Middle East and Africa) for the prevention of relapse in recurrent NIU- PS in those territories. The Product Rights Agreement also excludes any rights to YUTIQ for the treatment and prevention of chronic NIU- PS in China and certain other countries and regions in Asia, which rights are subject to a pre-existing exclusive license between EyePoint Parent and Ocumension. We have incurred and expect to continue to incur significant expenses: • to continue to support our sales efforts in the U. S., Germany, Portugal, the U. K. and Ireland; • to pursue the regulatory and reimbursement approval for ILUVIEN in other countries for both DME and NIU- PS; • to grow our operational capabilities; • to support our NEW DAY Study and SYNCHRONICITY Studies; and • to support our NIU- PS study in pediatric patients. These represent a significant investment in the commercial and regulatory success of ILUVIEN-our products, which is uncertain. If we or our distributors do not successfully maintain our sales in countries where we are approved to sell ILUVIEN-our products or our distributors do not successfully commence and grow our sales of ILUVIEN-our products in other countries where we are seeking to begin selling ILUVIEN-our products or have recently done so, our business may be seriously harmed. In addition, we may experience delays and unforeseen difficulties in the commercialization of ILUVIEN-our products, including unfavorable pricing or reimbursement levels in certain countries that could negatively affect our ability to increase revenues. We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do. The development and commercialization of new drugs is highly competitive, and the commercial success of ILUVIEN-our products or any of our future products or product candidates will depend on several factors, including our ability to differentiate any such products or product candidates from our competitors' current or future products. We face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide with respect to ILUVIEN-our current products and to any future products or product candidates that we may develop or commercialize in the future. Our commercial opportunities for ILUVIEN-our current products will be reduced or eliminated if our competitors develop or market products that: • are more effective; • receive better reimbursement terms; • have higher rates of acceptance by physicians; • have fewer or less severe adverse side effects; • are better tolerated; • are more adaptable to various modes of dosing; • have better distribution channels; • are easier to administer; or 17 • are less expensive, including a generic version of ILUVIEN-our products. Many pharmaceutical companies, biotechnology companies, public and private universities, government agencies and research organizations actively engage in research and development of products, some of which may target the same indications as ILUVIEN-our current products or any future products or product candidates. Our competitors include larger, more established, fully integrated pharmaceutical companies and biotechnology companies that have substantially greater capital resources, existing competitive products, larger research and development staffs and facilities, greater experience in drug development and in obtaining regulatory approvals and greater marketing capabilities than we do. Genentech, Novartis, Regeneron and AbbVie (Allergan) provide a short- term therapy that competes with ILUVIEN-our current products. 16 Our business is subject to political, economic, legal, and social risks, which could adversely affect our operations and financial position. There are significant regulatory, economic and legal barriers in markets in the United States-U. S. and outside the United States-U. S. that we must overcome. Changes in United States-U. S. social, political, regulatory, and economic conditions or in laws and policies governing foreign trade, manufacturing, development, and investment, and any negative sentiments towards the United States-U. S. as a result of such changes, could adversely affect our business. Concerns over economic weakness, including trade wars, unemployment, and continuing inflation and interest rate increases; natural disasters, public health epidemics or pandemics, such as the COVID- 19 pandemic, and actions taken in response to such events; supply chain delays and disruptions; and policy priorities of the U. S. presidential administration, to continued volatility and diminished expectations for the economy and markets. Additionally, concern over geopolitical issues may also contribute to prolonged market volatility and instability. For example, the ongoing conflict-conflicts between Russia and Ukraine and Israel and Hamas could lead to disruption, instability, and volatility in global markets and industries. It is not possible to predict the U. S. government and other-- the governments in jurisdictions have imposed severe economic broader or longer- term consequences of these conflicts, which could include further sanctions and export controls against Russia and Russian interests, have removed Russia from the Society for Worldwide Interbank embargoes, regional instability, energy shortages, geopolitical shifts and adverse effects on macroeconomic conditions, security conditions, currency exchange rates and Financial financial markets Telecommunication payment (SWIFT) system, and have threatened additional sanctions and controls. Such geopolitical instability The ultimate impact of these measures, as well as potential responses to them by Russia, is unknown. Any changes related to these and uncertainty other factors could adversely affect our business, both in the United States-U. S. and internationally. If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, it will impair our ability to commercialize ILUVIEN-our products and identify develop and commercialize any future products or product candidates. We depend on the principal members of our management team, including Richard S. Eiswirth, Jr., our President and Chief Executive Officer, Philip Ashman, Ph. D., our President of International Operations, Elliot Maltz, our Chief Financial Officer, Todd Wood, our President of U. S. Operations, Jason Werner, our Chief Operating Officer and Senior Vice President Commercial Operations Europe, Russell Skibsted, our Chief Financial Officer, and David Holland, our Chief Marketing Officer and Senior Vice President Corporate Communications and Managed Markets. These executives have significant ophthalmic, regulatory industry, sales and marketing, operational and / or corporate finance experience. From time to

time, there have been and may in the future be changes in our executive management team resulting from the hiring or departure of executives, which could disrupt our business. The loss of any such executives or any other principal member of our management team may impair our ability to market **HUVIEN our products** and identify, develop and commercialize any future ophthalmic products or product candidates. In addition, future growth may require us to hire a significant number of qualified technical, commercial and administrative personnel. We face intense competition from other companies and research and academic institutions for the qualified personnel we need in our business. For example, in 2019 our revenues in the U. S. market were negatively affected by a competitor's hiring some of our key sales personnel. We may need to invest significant amounts of cash and equity to attract and retain new and existing employees and we may never realize returns on these investments. If we are not able to effectively increase and retain our talent, our ability to achieve our strategic objectives will be adversely impacted, and our business will be harmed. Employees may be more likely to leave us if the shares of our capital stock they own or the shares of our capital stock underlying their equity incentive awards have significantly reduced in value. If we cannot continue to attract and retain, on acceptable terms, the qualified personnel necessary for the continued development of our business, we may not be able to sustain or grow our operations. We may not be successful in our efforts to expand the number of ophthalmic products we sell. In the future, we may choose to commercialize one or more new ophthalmic products in addition to **HUVIEN our current products**. We may seek to do so by establishing an internal research program or through licensing or otherwise acquiring the rights to potential new products and future product candidates for the treatment of ophthalmic disease. A significant portion of the research that we may choose to conduct may involve new and unproven technologies. Research programs to identify new disease targets and product candidates require substantial technical, financial and human resources, whether or not we ultimately identify any candidates. Any future research programs may initially show promise in identifying potential products or product candidates, yet fail to yield products or product candidates for clinical development for a number of reasons, including: • the research methodology used may not be successful in identifying potential products or product candidates; or **18** • we may learn after further study that potential products or product candidates have harmful side effects or other characteristics that indicate they are unlikely to be effective. We may be unable to license or acquire suitable products or product candidates or products from third parties for a number of reasons. In particular, the licensing and acquisition of pharmaceutical products is highly competitive. Several more established companies are also pursuing strategies to license or acquire products in the ophthalmic field. These established companies may have a competitive advantage over us due to their greater size, resources and development and commercialization capabilities. Other factors that may prevent us from licensing or otherwise acquiring suitable products or product candidates include the following: **17** • we may be unable to license or acquire the relevant technology on terms that would allow us to make an appropriate return from the product; • we may need to obtain our lender's consent to any significant payment or potential payment in conjunction with a license of acquisition of technology; • companies that perceive us to be their competitors may be unwilling to assign or license their product rights to us; or • we may be unable to identify suitable products or product candidates within our areas of expertise. Additionally, it may take greater human and financial resources to develop suitable potential products or product candidates through internal research programs or by obtaining rights than we will possess, thereby limiting our ability to develop a diverse product portfolio. If we are unable to develop suitable potential product candidates through internal research programs or by obtaining rights to novel therapeutics from third parties, opportunity for future growth could be limited. Our internal information technology systems, or those of our third-party contract research organizations (CROs) or other contractors or consultants, may fail or suffer **security-cybersecurity threats or** breaches, loss or leakage of data and other disruptions, which could result in a material disruption of certain parts of our business, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business. We depend on information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information, including intellectual property, proprietary business information and personal information. Maintaining the confidentiality and integrity of that confidential information is essential to our business. We also have outsourced elements of our operations to third parties, and as a result we work with a number of third-party contractors that have access to some of our confidential information. Although we have implemented security, backup and recovery measures, our internal information technology systems and those of our third-party manufacturers, CROs and other contractors or consultants **are potentially may be** vulnerable to **breakdown or cybersecurity attacks, computer viruses (including worms, malware, ransomware and other damage destructive or interruption from: -disruptive software or denial of service attacks)**, service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners or other third parties, **and cyber physical or electronic break - ins and similar disruptions. We or our third- party manufacturers, CROs and other contractors and consultants could also experience directed attacks by malicious third parties intended to lead to interruptions and delays in our service and operations as well as loss , including cyber misuse, theft or release of proprietary, confidential, sensitive or otherwise valuable company or subscriber data or information. Such a cybersecurity attack, virus, break - in, disruption or attack could remain undetected for an extended period, could harm our business, financial condition or results of operations, be expensive to remedy, expose us to litigation and / or damage our reputation. Our insurance may not cover expenses** related threats of spoofed or manipulated electronic communications that lead to misdirected **such disruptions or unauthorized access fully** fraudulent payments, the deployment of harmful malware or **at all** ransomware, malicious websites, denial-of-service attacks, and social engineering and other means to adversely affect service reliability and threaten the confidentiality, integrity and availability of information. Any of the foregoing may compromise our system infrastructure or lead to data leakage. While we have not experienced any such cyber-related fraud, system failure, accident or security breach through the date of this report that has materially affected our business, we cannot assure that our and our vendors' data protection efforts and our and our vendors' investment in information

technology will prevent cyber- attacks by malicious third parties, significant breakdowns, data leakages, breaches in our systems or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition. For example, if such an event were to occur and cause interruptions in our operations or a direct financial loss due to misdirected or fraudulent payments, it could result in a material disruption of our business operations, including, distribution and manufacturing, or to a direct financial loss. We sell ILUVIEN in the U. S. primarily to two distributors and in Europe we use two logistics providers. **Subject to the Supply Agreement with EyePoint Parent, EyePoint Parent is responsible for manufacturing and exclusively supplying (subject to certain exceptions) to us agreed- upon quantities of YUTIQ necessary for us to commercialize YUTIQ in the U. S. during the term of the Product Rights Agreement. We may elect to manufacture YUTIQ after and an initial 18- month term following the date of the Product Rights Agreement, upon the satisfaction of certain conditions.** 19A security breach that impairs these distribution or logistics operations could significantly impair our ability to deliver our products to healthcare providers. In addition, **ILUVIEN is our products are** manufactured and tested by third parties, and a security breach that impairs these third parties could significantly impair our ability to procure **ILUVIEN our products** and deliver **it them** to our distributors in a timely manner. There can be no assurance that our or their efforts will detect, prevent or fully recover systems or data from all breakdowns, service interruptions, attacks or breaches of systems, any of which could adversely affect our business and operations and / or result in the loss of critical or sensitive data, which could result in financial, legal, business or reputational harm to us or impact our stock price. In addition, the loss of clinical trial data for our product candidates or our post- market studies could result in delays in our regulatory approval efforts or marketing efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions or security breaches of our internal information technology systems or our vendors' technology systems could adversely affect or result in the loss of, misappropriation of, unauthorized access to, use of, disclosure of or the prevention of access to our confidential information, including trade secrets or other intellectual property, proprietary business information and personal information of our employees and patients in studies conducted on our behalf, which could result in financial, legal, business and reputational harm to us. For example, any such event that leads to unauthorized access to, use of or disclosure of ~~personal~~ -- **personal** information, including personal information regarding our employees or information we may have regarding patients, could harm our reputation directly, compel us to comply with federal and state breach notification laws and foreign law equivalents, subject us to mandatory corrective action and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business. Maintaining and growing our commercial infrastructure is a significant undertaking that requires productive, well- trained sales and marketing personnel, effective managers and substantial financial resources, and we may not be successful in our efforts to meet these needs. We anticipate that in the near term our ability to generate revenues will depend almost entirely on our ability to continue the successful commercialization of **ILUVIEN our current products**, both in the U. S. and ~~abroad~~ **internationally**. A commercial launch of **ILUVIEN our current products** is a significant undertaking that requires substantial financial and managerial resources. As our commercialization plans and strategies evolve, we will need to further expand the size of our organization by recruiting additional managerial, operational, sales, marketing, financial and other personnel. We may not be able to maintain and expand our commercial operation in a cost- effective manner or realize a positive return on this investment. In addition, we have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize **ILUVIEN our current products** or any future products include: • our inability to recruit and retain adequate numbers of effective sales and marketing personnel or maintain our sales and marketing infrastructure; • our inability to successfully enter into additional collaboration arrangements with third parties; • the inability of sales personnel to obtain access to or persuade adequate numbers of ophthalmologists to prescribe our products; • the lack of complementary products or additional labeled indications for **ILUVIEN our current products** to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and • unforeseen costs and expenses associated with maintaining and growing a commercial organization. Additionally, we may encounter unexpected or unforeseen delays in expanding our commercial operations that delay the commercial launch in one or more countries in which **ILUVIEN has our current products have** received marketing ~~authorization~~ **authorizations**. These delays may increase the cost of, and the resources required for successful commercialization of, **ILUVIEN our current products**. Further, a delay in the commercial launch of **ILUVIEN our current products** in certain jurisdictions could result in the withdrawal of our marketing or regulatory authorization for **ILUVIEN our current products** in those jurisdictions, including certain EEA member states where **ILUVIEN has our current products have** already received marketing ~~authorization~~ **authorizations**. Clinical trials for our products may not generate the outcomes we expect, may take longer or be more costly to complete than we anticipate. From time to time, we initiate or participate in clinical trials for **ILUVIEN our products** and may in the future participate in clinical trials or studies for other products. The timing of patient enrollment in these trials, and related costs, can be unpredictable, and any such trials or studies may be more expensive or take longer than we expect. Data from clinical trials are not always conclusive. Even if successful, these studies and trials may fail to change physician prescribing practices. ~~In~~ **addition, the ongoing COVID-19 pandemic can make the conduct of clinical trials more challenging given the paramount importance of adequate safety monitoring, collection of data and distribution of study drug, all of which are traditionally achieved by in- person visits. Challenges may continue to arise from site closures, site staffing shortages, potential interruptions to the supply chain for investigational products, or other considerations if site personnel or trial participants become infected with COVID-19. We may also experience a shortage of supplies and materials or a suspension of services from third parties.** ~~The~~ **20The** NEW DAY Study may fail to demonstrate the efficacy of ILUVIEN as baseline therapy in patients with early DME, fail to generate data demonstrating the benefits of ILUVIEN when compared to the current leading therapy for DME, take longer or be more costly to complete than we currently anticipate or fail to change physician prescribing practices. We are

conducting our NEW DAY Study, which is a multicenter, single-masked, randomized, controlled trial designed to generate prospective data evaluating ILUVIEN as a baseline therapy in the treatment of DME and demonstrate its potential advantages over the current standard of care of repeat anti-VEGF (aflibercept) injections. The NEW DAY Study is **fully planned to enroll 300** ~~enrolled approximately as of May 2023 with 300~~ treatment-naïve, or almost naïve, DME patients in approximately **40-42** sites around the U. S. ~~As of February 28, 2023, we have enrolled 261 DME patients in this study.~~ The NEW DAY Study may fail to demonstrate the efficacy of ILUVIEN as baseline therapy in patients with early DME, fail to generate data demonstrating the benefits of ILUVIEN when compared to the current leading therapy for DME, **or** take longer or be more costly to complete than we currently anticipate, ~~including due to complications from the ongoing COVID-19 pandemic,~~ and / or fail to change physician prescribing practices despite a successful result. The occurrence of any of these events could materially and adversely affect our business, financial condition and cash flows, and results of operations. ~~19~~ **We** may acquire additional businesses or form strategic alliances in the future, and we may not realize the benefits of those acquisitions or alliances. We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing ~~ILUVIEN-based~~ business, including adding new products in the ophthalmic field. The identification of suitable acquisition or alliance candidates can be difficult, time-consuming, and costly, and we may not be able to complete these transactions on favorable terms, if at all. If we acquire businesses with promising markets or ophthalmic products, we may be unable to realize the benefit of acquiring those businesses if we are unable to successfully integrate them with our existing operations and company culture. We may have difficulty in developing, manufacturing and marketing the ophthalmic products of a newly acquired company that enhances the performance of our combined businesses or product lines to realize value from expected synergies, and the process of integrating acquired businesses or products may create unforeseen operating difficulties and expenditures. We cannot assure that, following an acquisition or strategic alliance, we will achieve the revenues or other results that justify the transaction. If we fail to successfully manage our international operations, our business, operating results and financial condition could suffer. Our international operations require significant management attention and financial resources. Our international operations today cover the U. K. and much of Europe and the Middle East. There is a high level of regulation in all markets where ~~ILUVIEN is~~ **our current products are** sold and great diversity in how those markets operate. Consequently, experience and expertise is vital in understanding the market dynamics of each country, the rules and regulations in place governing the sale of medicines, the codes of practice governing promotion of medicines, different currencies, the financial frameworks applying to taxation (both corporate and ~~VAT~~ **value-added tax**) and the need to communicate in different languages. There is always a risk of loss of expertise through attrition of key roles within these international areas. Moreover, we rely on distributors in many countries to provide adequate levels of experience and expertise on our behalf. We seek to monitor and manage these relationships appropriately, including through a quarterly “Joint Steering Committee” process to address business issues and assess risks in each of these markets. We believe that China and the Western Pacific may become substantial markets for us under our license agreement with Ocumension ~~Therapeutics~~, which is currently working through regulatory filings ~~and plans to commence a real-world study estimated to start later in 2023.~~ **Additionally, they plan to begin a phase III study for the Chinese market in the second half of 2023.** We cannot assure that these efforts will ultimately prove to be successful, however, particularly in light of the currently strained trade and other relationships between the U. S. and China. In addition, there are many risks inherent in international business activities, including: • extended collection timelines for accounts receivable and greater working capital requirements; • multiple, conflicting legal systems and unexpected changes in legal requirements such as privacy and data protection laws and regulations, employment laws, regulatory requirements and other governmental approvals, permits and licenses; • tariffs, export restrictions, trade barriers and other regulatory or contractual limitations on our ability to sell or develop our product in certain foreign markets; • changes in currency exchange rates; • currency transfer and other restrictions and regulations that may limit our ability to sell ILUVIEN or repatriate profits to the ~~United States~~ **U. S.**; • difficulties adapting to new cultures, business customs, and legal systems; • trade laws and business practices favoring local competition; • potential tax issues, including restrictions on repatriating earnings, resulting from multiple, conflicting and complex tax laws and regulations; • weaker intellectual property protection in some countries; • natural disasters, political, economic, and social instability, including the effects of ongoing ~~United States~~ **U. S.** - China diplomatic and trade friction and social unrest in China and the recent ~~conflict~~ **conflicts** between Russia and Ukraine, ~~Israel~~ and ~~Hamas~~, and ~~global~~ **global** sanctions imposed in response thereto, the possibility of a wider European or global conflict, or other war or terrorist activities or the threat of war and terrorism; and • adverse economic conditions, including increasing inflation and the stability and solvency of business financial markets, financial institutions and sovereign nations. In addition, compliance with foreign and U. S. laws and regulations that are applicable to our international operations is complex and may increase our cost of doing business in international jurisdictions, and our international operations could expose us to fines and penalties if we fail to comply with these regulations. These laws and regulations include import and export requirements, U. S. laws such as the Foreign Corrupt Practices Act, and local laws prohibiting corrupt payments to governmental officials. Although we have implemented policies and procedures designed to help ensure compliance with these laws, there can be no assurance that our employees, partners and other persons with whom we do business will not take actions in violation of our policies or these laws. Any violations of these laws could subject us to civil or criminal penalties, including substantial fines or ~~20~~ **prohibitions** on our ability to offer our products in one or more countries, and could also materially and adversely harm our business and financial condition. **Adverse weather conditions, natural disasters and the effects of climate change could disrupt our manufacturers’ supply chains and adversely impact our sales and financial performance. Adverse weather conditions and natural disasters may affect our manufacturers’ supply chains, which could negatively impact our ability to source materials and components to make our products and, in more severe cases, such as hurricanes, earthquakes, floods, droughts, tornadoes or blizzards, eliminate the availability, or significantly increase the cost, of the components to make our products, sometimes for prolonged periods of time.** The **response of**

federal COVID-19 pandemic has had, **state** and may continue to have, certain negative impacts on our business, and those impacts may have an **and local governmental bodies and agencies to climate change through regulations, mandates, reporting and disclosure requirements, taxes or levies could materially increase our cost to operate or obtain product components at a reasonable price, resulting in a material** adverse effect on our **financial** results. **Any** of operations, **these situations could materially and adversely harm our business and** financial condition and cash flows. The public health crisis caused by the COVID-19 pandemic and the measures taken by governments, health authorities, businesses, and the public at large to limit the COVID-19 pandemic's spread have had, and may continue to have, certain negative effects on, and present certain risks to, our business. In 2020 and 2021, we experienced decreases in sales of ILUVIEN in the U. S. and in our international markets that have been affected by the COVID-19 pandemic, though sales recovered in 2022. The sales decreases resulted from, among other things, limitations on in-person access to physicians and patient behavior, particularly in light of governmental authorities citing diabetes as a factor that places a person at higher risk for severe illness from COVID-19. If the COVID-19 pandemic intensifies again, its negative effect on our sales and thus our liquidity and financial condition could be more prolonged and may be severe. Financial uncertainty associated with the adverse effects of the ongoing COVID-19 pandemic, and the duration of those effects, could have an impact in future periods on certain estimates used in the preparation of our quarterly financial results, including impairment of intangible assets, the income tax provision and realizability of certain receivables. Other effects or possible effects of the ongoing COVID-19 pandemic on us include: • Limitations on travel have curtailed our in-person marketing activities in the past and may again do so if reimposed. • Restrictions placed on regulatory and pricing bodies may delay or defer market access for ILUVIEN as we seek to secure reimbursement. • While most of our personnel have returned to work in the office, we may in the future experience reductions in productivity and disruptions to our business routines if a large percentage of our employees again works remotely, whether in the U. S. or in Europe. • The manufacturing or distribution of the ILUVIEN insert or applicator may be disrupted by government action related to COVID-19 or by the effect of the COVID-19 pandemic on our manufacturers' or distributors' workforces or supply chains, which may lead to product shortages. • We may fail to plan appropriately to meet the demand of our customers for ILUVIEN, which could lead either to ILUVIEN being out of stock or excessive inventory. Any of the above events could have an adverse effect on our results of operations, financial condition and cash flows.

Manufacturing Risks and Dependence on Third Parties We rely on third parties to manufacture and test **ILUVIEN our products**, and our business would be seriously harmed if any of these third parties is unable to satisfy our demand, given that obtaining these products or services from alternative sources can require a long transition period. We do not have, nor do we currently intend to establish, in-house manufacturing capability. We depend entirely on, and have agreements with, a single third-party manufacturer for each of: • the manufacture of **ILUVIEN our products'** s active pharmaceutical **ingredient ingredients**, • the manufacture of the **ILUVIEN our products'** applicator, • the manufacture of the **ILUVIEN our products'** **implant implants**, final assembly of the **injector injectors** with the **implant implants** and release testing in the U. S., and • the quality release testing of ILUVIEN in the EEA **and for the U. K.** If any of these third-party manufacturers breaches its agreement, is unable to meet its contractual or quality requirements or becomes unwilling to perform for any reason, we may be unable, in a timely manner or at all, to locate alternative acceptable manufacturers or testing facilities, as applicable, enter into favorable agreements with them and ensure that they are approved by the applicable regulatory authorities, such as the **U. S. Food and Drug Administration (FDA)**. For example, in the first quarter of 2020, we suffered from a supply shortage of ILUVIEN due in part to an equipment issue at our third-party manufacturer. **Further Furthermore**, all of our manufacturers rely on additional third parties for the manufacture of component parts. Any inability to acquire sufficient quantities of the active pharmaceutical **ingredient ingredients**, **the ILUVIEN our products'** implants or **the ILUVIEN our products'** applicator **applicators** in a timely manner from these third parties could delay commercial production of **ILUVIEN our current products**. Moreover, staffing and supply chain difficulties, which may be intensified by resurgences of the ongoing COVID-19 pandemic, may make it more difficult for our third-party manufacturers to provide sufficient quantities of their respective materials in a timely manner. Any such difficulties or delays could adversely affect our ability to fulfill demand for **ILUVIEN our current products**, which could in turn adversely affect our revenue, operations and cash flow. We rely on third parties for several important aspects of our business and have significant customer concentration. We rely heavily upon our third-party contractors, suppliers and distributors. Especially during challenging and uncertain times like the present, there may be disruptions or delays in the performance of these third parties. We rely entirely on third **parties -- parties** to manufacture, assemble and test our **ILUVIEN** applicators, as described in "Business — Manufacturing." We also rely on distributors for a majority of our sales of **ILUVIEN our current products**. We sell **ILUVIEN** to two large pharmaceutical distributors in the U. S., which accounted for **70 % and** 63 % of our consolidated product revenues in **2023 and** 2022, **respectively**. These same two customers accounted for approximately **70 % and** 71 % and **68 %** of our consolidated accounts receivable at December 31, **2023 and** 2022 **and** 2021, respectively. Internationally, our distributors produced approximately **43 % and** 39 % of our international product revenues in **2023 and** 2022, **respectively**. If the business relationship with any such distributor is terminated, whether through industry consolidation or otherwise, and we are unable to find a suitable replacement, or if any large customer defaults in their obligation to pay, our **operations** **22operations** and operating results could be materially adversely affected. These distributors also are not subject to any minimum sales requirements or obligations to market **ILUVIEN our products** to their customers. In turn, distributors could reduce their sales efforts for **ILUVIEN our products** or choose to terminate their representation of us. They may also fail to perform their obligations under the agreements with us. Additionally, in **the certain** Nordic **Region countries** we operate with the support of an exclusive wholesaler to support tendering processes in hospitals. The replacement or poor performance of this wholesaler, or our inability to collect accounts receivable from this wholesaler, could also materially and adversely affect our results of operations and financial condition. If one or more of our key third-party contractors, suppliers, manufacturers and / or distributors fail or are unable to satisfy their commitments to us, or if any of these key third-party relationships are terminated,

our business and results of operations could be adversely affected. Materials necessary to manufacture **ILUVIEN our current products** may not be available on commercially reasonable terms, or at all. We rely on our manufacturers to purchase materials from third-party suppliers necessary to produce **ILUVIEN our products**. Suppliers may not sell these materials to our manufacturers when needed or on commercially reasonable terms. We do not have any control over the process or timing of our manufacturers' acquisition of these materials. If our manufacturers are unable to obtain these materials in sufficient amounts, our sales of **ILUVIEN our products** would be hampered or there would be a shortage in supply, which would materially affect our ability to generate the revenues from the sale of **ILUVIEN our products** that we expect. Moreover, although we have agreements with our suppliers for the supply of the active pharmaceutical ingredient **ingredients** in **ILUVIEN our products**, the commercial production of the **ILUVIEN implant implants** and the commercial production of the **ILUVIEN our products' applicator-applicators**, the suppliers may be unable to meet their contractual or quality requirements or choose not to supply us in a timely manner or in the minimum guaranteed quantities. If our manufacturers are unable to obtain these essential supplies, their ability to manufacture **ILUVIEN our products** and thus ~~our the~~ supply of **ILUVIEN our products** for sale would be delayed, which could significantly reduce ~~our the~~ sales of **ILUVIEN our products** and have an adverse impact on our business. We may incur higher costs in acquiring component parts for the **ILUVIEN our products' inserter-inserters** and **insert-inserts** as a result of increases in applicable inflationary indexes specified in our contracts with manufacturers. Moreover, economic or political instability or disruptions, such as the **conflict-conflicts in-between Russia and Ukraine and Israel and Hamas**, could negatively affect our manufacturers' supply chains or further increase our costs. Financial Risks Our existing cash may be inadequate to fund our operations and support our growth. As of December 31, ~~2022~~ **2023**, we had approximately \$ ~~5.12~~ **3.1** million in cash and cash equivalents. We raised gross proceeds of \$ ~~12.78~~ **0.6** million in ~~March~~ **2023** through the sale of shares of our Series B Convertible Preferred Stock and warrants to purchase common stock to certain institutional investors **and received \$ 22.5 million loan proceeds through amendments to an existing loan agreement. \$ 75.0 million was utilized for the upfront payment in acquiring YUTIQ.** Whether ~~this amount~~ **current levels of liquidity** will be sufficient to **meet contractual obligations**, fund our operations and support our growth will be determined by many factors, some of which are beyond our control, and we may need additional capital ~~to fund our operations and support our growth sooner than we might anticipate~~. These factors include: • the level of continued success of the commercialization of **ILUVIEN our products** in the U. S., and in our international markets; • expenses relating to the commercialization of **ILUVIEN our products**; • our research, development and general and administrative expenses; • the timing of approvals, if any, of **ILUVIEN our products** for additional indications or in additional jurisdictions; • the timing of and extent to which we enter into, maintain and derive revenues from licensing agreements, including agreements to license **ILUVIEN our products** in additional countries or regions; research and other collaborations; joint ventures; and other business arrangements; • the timing of and extent to which we acquire, and our success in integrating, products or companies; • regulatory changes and technological developments in our markets; • increasing inflation; and • the extent to which we can manage the use of cash in our business operations. If we need additional capital to fund our operations and support our growth and we are unable to obtain that capital as noted below, our business may suffer. We may need to raise additional capital to fund and grow our business, and in that event we may be unable to do so on commercially reasonable terms, the terms on which we obtain the capital may restrict our operations and if the capital we raise is equity or a debt security that is convertible into equity, our stockholders' investment could be diluted. For the reasons described above, we may need to raise alternative or additional financing to fund our operations and support growth. General market conditions or the market price of our common stock may not support capital-raising transactions such as an additional public or private offering of our common stock or other securities. If we need additional financing, we may seek to ~~fund~~ **fund** our operations through the sale of equity securities, additional debt financing and strategic collaboration agreements. We cannot be sure that additional financing from any of these sources will be available when needed or that, if available, the additional financing will be obtained on terms favorable to us or our stockholders. In addition, our ability to raise additional ~~capital~~ **capital** may depend upon obtaining stockholder approval. There can be no assurance that we will be able to obtain stockholder approval for a capital raise if it is necessary under applicable Nasdaq **Global Market ("Nasdaq")** rules. If we are unable to obtain adequate financing or financing on terms satisfactory to us, when we require it, our ability to continue to fund and grow our business would be significantly limited. If we raise additional funds by selling shares of our capital stock or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our common stock. If we attempt to raise additional funds through strategic collaboration agreements, we may not be successful in obtaining those agreements, or in receiving milestone or royalty payments under those agreements. If we raise additional funds by incurring additional debt (assuming our lenders would permit such debt, which would be subordinated to the debt outstanding under our credit facility), the terms of the debt may include significant installment payments as well as covenants and specific financial ratios that may restrict our ability to continue to commercialize ILUVIEN or commercialize any future products or product candidates or otherwise successfully operate our business. Our ability to access any existing or future capital is also dependent on the condition of the banking system and financial markets. For example, in March 2023, the Federal Deposit Insurance Corporation ("**FDIC**") took control and was appointed receiver of Silicon Valley Bank ("**SVB**") and Signature Bank ("**Signature**"). As of the date of this report, we do not have direct exposure to SVB or Signature, but we cannot predict the broader impact or follow-on effects of these insolvencies. If other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash, cash equivalents and investments may be threatened and could have a material adverse effect on our business and financial condition. The terms of our credit facility require us to meet certain operating covenants and restrict our operating and financial flexibility, and any breach of the covenants in that agreement, if the lenders elected to accelerate the due date of the loan, could significantly harm our business and prospects and lead to the liquidation of our business. Our Loan and Security Agreement dated December 31,

2019, with SLR Investment Corp. (“SLR”) as collateral agent, and the lenders party thereto, including SLR as a lender (as amended from time to time, the “2019 Loan Agreement”) contains certain operating covenants and restricts our operating and financial flexibility. The 2019 Loan Agreement is secured by a lien covering all of our U. S. assets (and certain ownership interests in one of our foreign subsidiaries), including our intellectual property. The 2019 Loan Agreement contains customary affirmative and negative covenants and events of default. Affirmative covenants include covenants requiring us to comply with applicable laws, maintain our legal existence, deliver certain financial reports and maintain insurance coverage. Negative covenants restrict our ability to transfer any part of our business or property, to change our business or key management, to incur additional indebtedness, to engage in mergers or acquisitions, to pay dividends or make other distributions, to make investments, to create other liens on our assets and to allow revenues from the sale of ILUVIEN to fall below certain minimums, in each case subject to customary exceptions. If an event of default under the 2019 Loan Agreement occurs, SLR may accelerate all of our repayment obligations and take control of our pledged assets, potentially requiring us to raise additional financing, renegotiate the 2019 Loan Agreement on terms less favorable to us or immediately cease operations. Any declaration by SLR of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline significantly. Any declaration by SLR of an unwaived event of default could significantly harm our business and prospects and could cause the price of our common stock to decline significantly. Further, if we were liquidated, the lenders’ right to repayment would be senior to the rights of our stockholders. In ~~During each of the past six-month periods ended September 30, 2021 and December 31, 2021,~~ we did not generate sufficient revenue to meet the trailing six-month revenue covenant included in the 2019 Loan Agreement (the “Revenue Covenant”). For each such six-month period ~~that we did not meet the Revenue Covenant in the past~~, the lenders provided a consent that permitted us not to maintain the Revenue Covenant ~~as of September 30, 2021 and December 31, 2021, respectively,~~ and waived any event of default that may have occurred or may be deemed to have occurred. We can offer no assurances, however, that the lenders will accommodate such a request for a consent and waiver if in the future we fail to meet the Revenue Covenant or any other covenant that would result in an event of default under the 2019 Loan Agreement. We expect to comply with the Revenue Covenant at the next reportable date, and throughout ~~2023-2024~~. However, if we fail to comply with the Revenue Covenant and the lenders do not provide a consent and waiver, acceleration of the maturity of the loan is one of the remedies available to the lenders. If the lenders accelerate the maturity of the loan, we would be forced to find alternative financing or enter into an alternative agreement with the lenders. We cannot be sure that alternative financing will be available when needed or that, if available, the alternative financing could be obtained on terms that are not significantly detrimental to us or our stockholders. ~~23~~ We ~~We~~ have incurred operating losses in each year since our inception ~~through and expect to continue to incur losses in~~ 2023. We have incurred recurring losses and negative cash flow from operations, and we have accumulated a deficit of \$ ~~415-418.45~~ million from our inception through December 31, ~~2022~~ ~~2023~~. Our ability to achieve profitability and positive cash flow depends on our ability to ~~maintain~~ ~~increase~~ revenue and contain our expenses. We are uncertain if we will achieve profitability and, if so, whether we will be able to sustain it. Our ability to maintain and increase revenue and achieve profitability depends on our ability to continue to successfully market and sell ~~ILUVIEN our products~~ in the geographic areas where we or our distributors offer ~~ILUVIEN our products~~. We cannot ~~assure~~ ~~24~~ ~~assure~~ that we will be profitable even if we successfully commercialize ~~ILUVIEN our current products~~ or future products or product candidates. Failure to become and remain profitable may adversely affect the market price of our common stock and our ability to raise capital and continue operations. ~~Our recurring losses from operations raise substantial doubt regarding our ability to continue as a going concern. Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern. In that regard, the audit report issued by our independent registered public accounting firm for the audit of our 2022 financial statements, included elsewhere in this report, includes an explanatory paragraph describing the existence of conditions that raise substantial doubt about our ability to continue as a going concern. There is no assurance that sufficient financing will be available to us when needed to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.~~ Our quarterly operating results and cash flows are expected to fluctuate significantly. We expect our operating results and cash flows to be subject to quarterly fluctuations. Our revenues and operating results will be affected by numerous factors, including: • the ongoing commercial success of ~~ILUVIEN our products~~ (or lack thereof); • inconsistent timing and ordering patterns from our U. S. distributors; • seasonality caused by insurance renewals for patients in the U. S. and by doctor and or patient absences due to holidays and vacations; • sales, marketing and medical affairs expenses; • the timing and amount of royalties, milestone payments or product purchases by our distributors; • our ability to obtain regulatory ~~approval~~ ~~approvals~~ of ~~ILUVIEN our products~~ in additional jurisdictions or for additional indications; • regulatory developments affecting ~~ILUVIEN our current products~~; our future product candidates or our competitors’ products; • the emergence of products or treatments that compete with ~~ILUVIEN our products~~; • variations in the level of expenses related to our products or future development programs; • the status of our clinical development programs; • our execution of collaborative, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements; • any lawsuit or intellectual property infringement in which we are or may become involved; • general economic and political conditions in our domestic and international markets, including inflation and fluctuations in supply chains; • global pandemics, such as COVID- 19, or other public health emergencies and the responses thereto; • unexpected events, including those resulting from climate change or geopolitical events; • the timing and recognition of stock-based compensation expense; and • the timing and amount of patient enrollments in our clinical studies, ~~including the NEW DAY Study~~ and related expenses. If our operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any fluctuations in our operating results or cash flows may, in turn, cause significant volatility in the price of our stock. We believe that comparisons of our quarterly financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance. Prolonged economic uncertainties or downturns, as

well as unstable market, credit and financial conditions, may exacerbate certain risks affecting our business and have serious adverse consequences on our business. Economic conditions, and uncertainty as to the general direction of the macroeconomic environment, are beyond our control. In recent years, the ~~United States~~ **U. S.** and other significant markets have experienced cyclical downturns and worldwide economic conditions remain uncertain, particularly as a result of increasing inflation and related market and macroeconomic responses including interest rate increases, the ~~ongoing~~ **COVID- 19** pandemic and ~~its related resurgences and variants, and the ongoing conflict~~ **conflicts between** ~~arising out of the Russian~~ **Russia and invasion of** Ukraine **and Israel and Hamas**. Economic uncertainty and associated macroeconomic conditions, including geopolitical tensions, escalating inflation, supply chain issues and the availability and cost of credit and government stimulus programs in the ~~United States~~ **U. S.** and other countries have contributed to increased market volatility or market declines, ~~24~~ **make** ~~it~~ **make** it extremely difficult for our partners, suppliers, and us to accurately forecast and plan future business activities. Sales of our products will depend, in large part, on reimbursement from government health administration authorities, private health insurers, distribution partners and other organizations in the U. S., Germany, Portugal, Ireland, the U. K. and other countries. Negative trends in the general economy in any of the jurisdictions in which we may do business may cause these organizations to be unable to satisfy their reimbursement obligations or to delay payment. In addition, health authorities in some jurisdictions may reduce reimbursements, and private insurers may increase their scrutiny of claims. A reduction in the availability or extent of reimbursement could negatively affect our product sales and revenue. ~~Exchange~~ **Exchange** rate fluctuations of foreign currencies relative to the U. S. Dollar could materially and adversely affect our business. Approximately ~~37~~ **30** % of our product revenues in ~~2022~~ **2023** were international. A substantial majority of our international revenues and expenses are denominated in British Pounds and Euros, and as such are sensitive to changes in exchange rates. We also have balances, such as cash, accounts receivable, accounts payable and accruals, that are denominated in foreign currencies. These foreign currency transactions and balances are sensitive to changes in exchange rates. Fluctuations in exchange rates of the British Pound and Euro in relation to the U. S. Dollar could materially reduce our future revenues as compared to prior periods. We do not seek to mitigate this exchange rate effect by using derivative financial instruments. To the extent we are unable to match revenues received in foreign currencies with costs paid in the same currency, exchange rate fluctuations in that currency could have a material adverse effect on our business and results of operations. As our international operations continue to grow, our risks associated with fluctuations in currency rates will become greater. New or revised tax regulations, unfavorable resolution of tax contingencies or changes to enacted tax rates could adversely affect our tax expense. As a multinational organization, we may be subject to taxation in several jurisdictions around the world with increasingly complex tax laws, the application, interpretation and enforcement of which can be uncertain. Changes in tax laws or their interpretations could result in changes to enacted tax rates and may require complex computations to be performed that were not previously required, significant judgments to be made in interpretation of the new or revised tax regulations and significant estimates in calculations, as well as the preparation and analysis of information not previously relevant or regularly produced. Future changes in enacted tax rates could negatively affect our results of operations. For example, the recently enacted Inflation Reduction Act of 2022 includes a minimum tax equal to fifteen percent of the adjusted financial statement income of certain corporations as well as a one percent excise tax on share buybacks, **which went** effective for tax years beginning in 2023. ~~It~~ **When effective, it** is possible that the minimum tax could result in an additional tax liability over the regular federal corporate tax liability in a given year based on differences between book and taxable income (including as a result of temporary differences). Relevant foreign taxing authorities may disagree with our determinations as to whether we have established a taxable nexus, often referred to as a “ permanent establishment ,” ~~”~~ or the income and expenses attributable to specific jurisdictions. In addition, these authorities may take aggressive tax recovery positions that the funds flows we process are subject to value added tax or goods and services tax. If disagreements with relevant taxing authorities on other unknown matters were to occur, and our position was not sustained, we could be required to pay additional taxes, interest and penalties, which could result in one- time tax charges, higher effective tax rates, reduced cash flows and lower overall profitability of our operations. Our tax returns and positions are subject to review and audit by federal, state, local and international taxing authorities. An unfavorable outcome to a tax audit could result in higher tax expense, thereby negatively affecting our results of operations and cash flows. We have recognized estimated liabilities on the balance sheet for material known tax exposures relating to deductions, transactions and other matters involving some uncertainty as to the proper tax treatment of the item. These liabilities reflect what we believe to be reasonable assumptions as to the likely final resolution of each issue if raised by a taxing authority. While we believe that the liabilities are adequate to cover reasonably expected tax risks, there can be no assurance that, in all instances, an issue raised by a tax authority will be finally resolved at a financial amount no more than any related liability. An unfavorable resolution, therefore, could negatively affect our financial position, results of operations and cash flows in the current and / or future periods. Our ability to use our net operating loss carry- forwards may be limited. As of December 31, ~~2022~~ **2023**, we had U. S. federal and state net operating loss (**“ NOL ”**) carry- forwards of approximately \$ ~~147~~ **146** ~~28~~ million and \$ ~~107~~ **106** ~~78~~ million, respectively. Except for the NOLs generated after 2017, the U. S. federal NOLs not fully utilized will expire at various dates between 2029 and 2037; most state NOL carry- forwards will expire at various dates between ~~2022~~ **2023** and ~~2042~~ **2043**. Under the Tax Cuts and Jobs Act of 2017, U. S. federal NOLs and some state NOLs generated after 2017 will carry forward indefinitely. These NOLs may be subject to further limitation based upon the final results of our Internal Revenue Code sections 382 and 383 analyses. Sections 382 and 383 of the Internal Revenue Code limit the annual use of NOL carry- forwards and tax credit carry- forwards, respectively, following an ownership change. NOL carry- forwards may be subject to annual limitations under Section 382 (or comparable provisions of state law) if certain changes in ownership of our company were to occur. In ~~25~~ **general** ~~general~~, an ownership change occurs for purposes of Section 382 if there is a more than 50 % change in ownership of a company over a 3- year testing period. We have determined that a Section 382 change in ownership occurred in ~~late~~ **December of 2015** **and in 2023**. As a result of ~~this~~ **these** ~~change~~ **changes** in ownership ~~ownerships~~, we estimated that

substantially all approximately \$18.6 million of our federal and state NOLs, NOL carry-forwards and approximately \$382,000 of federal tax credits generated prior to the 2023 change in ownership will be subject to Section 382 limitations and may not be fully utilized in the future. We are currently in the process of evaluating refining and finalizing these -- the Section 382 impact to calculations, and upon finalization, will determine if a write-off is necessary. The reduction to our NOL deferred tax asset due to the annual Section 382 limitation and the NOL carryforward period would result in an offsetting reduction in valuation allowance recorded against the NOL deferred tax asset. Therefore, the limitation does not affect the statements of operations for the periods presented. Any future changes in our ownership or sale of our stock, including our March 2023 financing, could further limit the use of our NOLs in the future. If we need to obtain alternative or additional financing to meet our liquidity requirements under the 2019 Loan Agreement and we raise those funds by selling additional equity, this could further limit the use of our NOLs in the future. Because 26Because our interest rate under the 2019 Loan Agreement is based on SOFR, a floating rate, we are exposed to the risks of higher interest rates, which could decrease our liquidity and capital resources and adversely affect our financial performance. Our interest rate under the 2019 Loan Agreement is based on SOFR, a floating rate. The Federal Reserve raised interest rates seven 11 times in since March 2022 and has indicated it may continue to do so to combat the effects of inflation, which is currently higher than it has been since the early 1980s. An increase in SOFR would increase our interest costs. Significant increases in our interest costs could materially and adversely affect our results of operations and our ability to pay amounts due under the 2019 Loan Agreement, and any increase in the interest we pay would reduce our cash available for working capital, acquisitions, and other uses. Regulatory RisksThe manufacture and packaging of pharmaceutical products such as ILUVIEN and YUTIQ are subject to the requirements of the FDA and similar foreign regulatory entities. If we or our third-party manufacturers fail to satisfy these requirements, our commercialization and regulatory approval efforts may be materially harmed. The FDA and similar foreign regulatory agencies regulate the manufacture and packaging of pharmaceutical products such as ILUVIEN and YUTIQ, which must be conducted in accordance with the FDA's current Good Manufacturing Practices (cGMP) and comparable requirements of foreign regulatory agencies. Only a limited number of manufacturers that operate under these cGMP regulations are both capable of manufacturing ILUVIEN our current products and willing to do so. If we or our third-party manufacturers fail to comply with applicable regulations, requirements or guidelines, the regulatory agencies could refuse to grant marketing approval of ILUVIEN our current products or any future products or product candidates and could impose sanctions on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. Failure of our manufacturers to maintain compliance could interrupt the production of ILUVIEN our current products, resulting in delays and additional costs that could significantly and adversely affect our business. Any significant delays in the manufacture of ILUVIEN our current products or issues with the quality of the product could materially harm our business and prospects. Changes in certain aspects of the manufacturing process or procedures require prior FDA review or approval of the manufacturing process and procedures in accordance with the FDA's cGMP regulations. There are comparable foreign requirements as well. This review may be costly and time-consuming and could delay or prevent the launch of a product. If we elect or are required to manufacture products at another facility, we will transfer the manufacturing to a registered medical device manufacturing company to seek to ensure that the new facility and the manufacturing process comply with cGMP and comparable foreign regulations. Any such new facility would also be subject to inspection. In addition, we would be required to demonstrate by physical and chemical methods, which are costly and time-consuming, that the product made at any new facility is equivalent to the product made at the former facility. The FDA or a foreign regulatory agency may require clinical testing to prove equivalency of the product manufactured at any new facility compared to the old facility, which would result in additional costs and delay. Further, we are required to complete testing on both the active pharmaceutical ingredient and on the finished product in the packaging that we propose for commercial sales. This includes testing of stability, identification of impurities and testing of other product specifications by validated test methods. In addition, our manufacturers are required to consistently produce our product in commercial quantities and of specified quality in a reproducible manner and document their ability to do so. This requirement is referred to as process validation. The FDA and similar foreign regulatory agencies may also implement new standards, or change their interpretation and enforcement of existing standards and requirements, for the manufacture, packaging or testing of products at any time. 26Regulatory -- Regulatory agencies may impose limitations on the indicated uses for which ILUVIEN our products may be marketed, or on our promotional activities, which would be adverse to our business. Any regulatory approval is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the applicable regulatory authorities, including the FDA in the U. S. and various regulatory authorities in Europe. If a regulatory agency approves ILUVIEN our products for only a limited indication, the size of our potential market for ILUVIEN our products will be reduced. ILUVIEN has received marketing authorization in numerous countries in the EEA and elsewhere in the world for the treatment of vision impairment associated with chronic DME considered insufficiently responsive to available therapies. In the U. S., Australia, Canada, Kuwait, Lebanon and the United Arab Emirates, the indication for ILUVIEN is different, as ILUVIEN is indicated for the treatment of DME in patients who have been previously treated with a course of corticosteroids and did not have a clinically significant rise in intraocular pressure. Either of these indications or future indications may limit the use of ILUVIEN to a narrower segment of the DME population than we believe is warranted. As a result, our potential revenues are now and may be in the future less than than they would be with broader indications for ILUVIEN. While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote the products is limited to 27to those indications that are specifically approved by regulatory authority. These "off-label" uses by physicians are common across medical specialties and may constitute an appropriate treatment for some patients in some circumstances. Regulatory authorities generally do not regulate the behavior of physicians in their choice of treatments.

Regulatory authorities do restrict, however, communications by pharmaceutical companies on the subject of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow regulatory authority rules and guidelines relating to promotion and advertising may cause the regulatory authority to suspend or withdraw an approved product from the market in the applicable country, require a recall or payment of fines, or impose sanctions that could include disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our business. In the U. S., **ILUVIEN-our current products** and any future products or product candidates may not remain commercially viable if we fail to obtain or maintain an adequate level of reimbursement for these products from: private insurers, the Medicare and Medicaid programs or other third-party payers. Our revenue from sales of **ILUVIEN-our current products** in the U. S. depends on our ability to maintain pricing and reimbursement guidelines at our desired levels. Those guidelines, however, may fall well below our current expectations. The same could also occur for any future products or product candidates we may develop that receive approval, if any. Sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third-party payers, such as government and private insurance plans. Third-party payers are increasingly challenging the prices charged for medical products and services. The Patient Protection and Affordable Care Act, as amended by the **Health Care and Education Affordability Reconciliation Act of 2010 (together, the ACA)**, significantly changed the way healthcare is financed by both governmental and private insurers. The provisions of the ACA became effective beginning in 2010, although some of its key provisions were altered through the Tax Cuts and Jobs Act enacted in December 2017. Through the date of this report, **U. S.** President Biden has enacted certain changes to Medicare reimbursement policies, and we cannot predict further changes that the Biden Administration may make to current federal reimbursement policies under this law and whether those changes will affect us. Changes to the ACA or any replacement law may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of **ILUVIEN-our current products** or new products. Any rebates, discounts, taxes, costs or regulatory or systematic changes on healthcare resulting from changes to the ACA may have a significant effect on our profitability in the future. We cannot predict whether the ACA will continue in its present form or what other laws or proposals will be made or adopted, or what impact these efforts may have on us. We expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce our profitability. Our list pricing in the U. S. for **ILUVIEN and for YUTIQ** is based upon the burden of DME **and NIU- PS, respectively**, the current pricing of approved therapies for DME **and NIU- PS**, our perception of the overall cost-to-benefit ratio of **ILUVIEN and NIU- PS, and** the pricing of other therapies. Due to numerous factors beyond our control, including efforts to provide for containment of healthcare costs, the U. S. may not support our current level of governmental pricing and reimbursement for **ILUVIEN and YUTIQ**, which would reduce our anticipated revenue **from ILUVIEN in the U. S.** In the U. S., the Medicare and Medicaid programs currently provide reimbursement for **ILUVIEN-our products**, but the reimbursement amount for **ILUVIEN-our products** could be modified in the future, and the types of patients for whom **ILUVIEN-our products are** reimbursed could be reduced to a smaller subset of patients. In addition, in some states, Medicare reimburses physicians for less than the cost of **ILUVIEN-our products**. In recent years, through legislative and regulatory actions, the federal government has made substantial changes to various payment systems under the Medicare program. Comprehensive reforms to the U. S. healthcare system were recently enacted, including changes to the methods for, and amounts of, Medicare reimbursement. The Biden administration may seek further reform of the Medicare program and the U. S. healthcare system. Some of these changes and reforms could result in reduced reimbursement rates for **ILUVIEN-our current products** and our future product candidates, which would adversely affect our business strategy, operations and financial results. Our business could also be adversely affected if retinal specialists are not reimbursed for the cost **27of of** the procedure in which they administer **ILUVIEN-our products** at a level that is satisfactory to them. Limitations on coverage could also be imposed at the local Medicare carrier level or by fiscal intermediaries. Our business could be materially adversely affected if the Federal Medicare program, or local Medicare carriers (MACS) or fiscal intermediaries were to make such a determination and deny or limit the reimbursement of **ILUVIEN-our products**. If the local contractors that administer the Medicare program are slow to reimburse retinal specialists for **ILUVIEN-our products**, that delay could ultimately affect the timing of payments to us, which would in turn adversely affect our working capital. In the U. S., almost all private insurers, including managed care organizations, have agreed to reimburse for **ILUVIEN-our products**, but the reimbursement amount could be modified in the future, and the types of patients for whom **ILUVIEN-our products are** reimbursed could be reduced to a smaller subset of patients. We expect that private insurers will consider the efficacy, cost effectiveness and safety of **ILUVIEN-our products** in determining whether to maintain approval for reimbursement for **ILUVIEN-our products** in the U. S. and at what level. Maintaining these approvals can be a time-consuming and expensive process. Our business would be materially adversely affected if we do not maintain approval for reimbursement of **ILUVIEN-our products** from private insurers on a timely or satisfactory basis or such approvals are changed to reduce the level of reimbursements. **We 28We** may experience pricing pressures in connection with the sale of **ILUVIEN-our products** due to the potential healthcare reforms discussed above, as well as the trend toward programs aimed at reducing healthcare costs, the increasing influence of health maintenance organizations, additional legislative proposals and the economic health of the U. S. economy. If reimbursement for our products is unavailable, limited in scope or amount or if pricing is set at unsatisfactory levels, our business could be materially harmed. In the European Economic Area (**"EEA"**) and the U. K., **ILUVIEN** and any future products or product candidates may not be commercially viable if we fail to obtain or maintain an adequate level of reimbursement for these products from any of the following: governments, private insurers or other third-party payers. In the EEA and the U. K., each country has a different reviewing body that evaluates reimbursement dossiers submitted by marketing authorization holders of new drugs and then makes recommendations as to whether or not the drug should be reimbursed. In these countries, pricing negotiations with governmental authorities can take 12 months or longer after

the receipt of regulatory approval. In some countries, to obtain reimbursement approval or pricing approval at a level that we believe is appropriate, we may be required to conduct a clinical trial that compares the cost-effectiveness of ILUVIEN to other available therapies. Limitations on reimbursement could be imposed at the national, regional or local level or by fiscal intermediaries in each country, either through the initial authorization process or at some point in the future. In addition, due to price referencing within the EEA, the U. K. and certain other countries, existing pricing in our current markets could be negatively affected by a change in pricing in a country where we currently have reimbursement or by a new price in a country where we obtain reimbursement approval in the future. We have been affected by such changes in the past, and any future cross-border price referencing could have a material adverse effect on our business. Our business could also be adversely affected if governments, private insurers or other reimbursing bodies or payers limit the indications for reimbursement approval to a smaller subset than we believe ILUVIEN is effective in treating or establish a limit on the frequency with which ILUVIEN may be administered that is less often than we believe would be effective. Those actions could limit our revenues and harm our business. Failure to comply with government regulations regarding the sale and marketing of our products could harm our business. Our and our distribution partners' activities, including the sale and marketing of our products, are subject to extensive government regulation and oversight, including regulation under the federal Food, Drug and Cosmetic Act and other federal and state statutes, along with requirements in Europe, such as the Medicines Act of 1968 in the U. K. In the U. S., we are also subject to the provisions of the Federal Anti-Kickback Statute, the Federal False Claims Act and several similar state laws, which prohibit payments intended to induce physicians or others either to purchase or arrange for or recommend the purchase of healthcare products or services. While the federal law applies only to products or services for which payment may be made by a federal healthcare program, state laws may apply regardless of whether federal funds may be involved. These laws constrain the sales, marketing and other promotional activities of manufacturers of drugs by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians and other potential purchasers of drugs. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent, or are for items or services that were not provided as claimed. Anti-kickback and false claims laws prescribe civil and criminal penalties for noncompliance that can be substantial, including the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid). Pharmaceutical and biotechnology companies have been the target of lawsuits and investigations alleging violations of government regulation, including claims asserting antitrust violations, violations of the Federal False Claim Act, the Anti-Kickback Statute, the Prescription Drug Marketing Act and other violations in connection with off-label promotion of products and Medicare and / or Medicaid reimbursement and claims under state laws, including state anti-kickback and fraud laws. In 28 Europe -- Europe, each country has different regulations that govern the promotional claims and activities of pharmaceutical and biotechnology companies. The violation and enforcement of these regulations by each country may result in heavy fines, further legal action, public reprimand, injunction and may include the loss of market authorization. While we have implemented a compliance program to assist with monitoring and complying with these activities and we strive to comply with these complex requirements, interpretations of the applicability of these laws to marketing practices are ever evolving. If any such actions are instituted against us or our partners and we or they are not successful in defending those actions or asserting our rights, those actions could have a significant and material adverse effect on our business, including the imposition of significant fines or other sanctions. Even an unsuccessful challenge could cause adverse publicity and be costly to respond to, and thus could have a material adverse effect on our business, results of operations and financial condition. The 29 The regulatory approval of ILUVIEN our products in any additional countries is uncertain, and our regulatory approval in certain countries is contingent on our ability to sell ILUVIEN our products in an appropriate time frame. Failure to obtain regulatory approval in additional foreign jurisdictions or maintain regulatory approval in jurisdictions where we have received regulatory approval but have not yet sold ILUVIEN our products would prevent us from marketing and commercializing ILUVIEN our products in those additional markets. ILUVIEN has received marketing authorization in the U. S., in numerous countries in Europe and in other places in the world as described above in "Business – Overview." We sell ILUVIEN directly in the U. S., Germany, the U. K., Portugal, Ireland, Denmark, Finland, Norway and Sweden. Our distributors will continue to sell ILUVIEN in the Middle East, Austria, Czech Republic, France, the Netherlands, Belgium, Luxembourg, Italy and, Spain and certain in 2023. In addition, beginning in April 2023, ILUVIEN will be sold by Horus Pharma in the Nordic countries (Sweden, Norway, Finland and Denmark) in 2024. When we received marketing authorization in the remaining countries in the EEA, those marketing authorizations required that we sell at least one ILUVIEN in those countries within three years or our license in those countries could be revoked unless we negotiate to extend the deadline. We intend to either sell one ILUVIEN in each of those countries or negotiate to extend the deadline, but we may not be able to make such a sale or extend the deadline, in which case our license in that country could be revoked. If our license in any of these countries is revoked, we will need to pursue marketing authorization again for that country, and we may be unsuccessful in that effort. In the U. S., YUTIQ is indicated for the treatment and prevention of chronic NIU- PS. Pursuant to the Product Rights Agreement with EyePoint Parent, we have the commercialization rights to YUTIQ in the entire world, except Europe, the Middle East and Africa as we had previously licensed from EyePoint rights to commercialize ILUVIEN in Europe, the Middle East and Africa for the prevention of relapse in recurrent NIU- PS in those territories. The Product Rights Agreement also excludes any rights to YUTIQ for the treatment and prevention of chronic NIU- PS in China and certain other countries and regions in Asia, which rights are subject to a pre-existing exclusive license between EyePoint Parent and Ocumension. We intend to continue to pursue market authorizations for ILUVIEN our products internationally in additional jurisdictions. To market our products in foreign jurisdictions, we will be required to obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. We may not receive the necessary approvals to commercialize ILUVIEN our products in any additional market. The process of obtaining regulatory approvals and clearances in jurisdictions where ILUVIEN is our

products are not approved will require us to expend substantial time and capital. Despite the time and expense incurred, regulatory approval is never guaranteed. The number of preclinical and clinical tests that will be required for regulatory approval varies depending on the drug candidate, the disease or condition for which the drug candidate is in development, the jurisdiction in which we are seeking approval and the regulations applicable to that particular drug candidate. Regulatory agencies can delay, limit or deny approval of a drug candidate for many reasons, including that: • regulatory agencies may interpret data from preclinical and clinical testing in different ways than we do; • regulatory agencies may not approve our manufacturing processes; • a drug candidate may not be safe or effective; • regulatory agencies may conclude that the drug candidate does not meet quality standards for stability, quality, purity and potency; and • regulatory agencies may change their approval policies or adopt new regulations. The applicable regulatory authorities may make requests or suggestions regarding our clinical trials, resulting in an increased risk of difficulties or delays in obtaining regulatory approval. For example, the regulatory authorities may not approve of certain of our methods for analyzing our trial data, including how we evaluate the relationship between risk and benefit. Additionally, the foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. For all of these reasons, we may not obtain additional foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA. If we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions (which could include civil or criminal penalties), private litigation and / or adverse publicity, which could negatively affect our operating results and business. We are subject to data protection laws and regulations. In the U. S., numerous federal and state laws and regulations, including state data breach notification laws, state health information and / or genetic privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of health related and other personal information. In California, the California Consumer Privacy Act (“CCPA”) establishes certain requirements for data use and sharing transparency, and provides California residents certain rights concerning the use, disclosure, and retention of their personal data. The California Privacy Rights Act (CPRA) currently in effect, significantly amends the CCPA. Virginia, Colorado, Utah, and Connecticut have ~~29 enacted~~ **enacted** privacy laws similar to the CCPA that impose new obligations or limitations in areas affecting our business, **and similar laws are under consideration in other states**. These laws and regulations are evolving and subject to interpretation and may impose limitations on our activities or otherwise adversely affect our business. The obligations to comply with the CCPA and evolving legislation may involve, among other things, updates to our notices and the development of new processes. We may be subject to fines, penalties, or private actions in the event of non-compliance with such laws. ~~In 30~~**In** addition, we may obtain health information from third parties (e. g., healthcare providers who prescribe our product) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, (collectively, “HIPAA”). HIPAA imposes privacy and security obligations on covered entity health care providers, health plans, and health care clearinghouses, as well as their “business associates” — certain persons or entities that create, receive, maintain, or transmit protected health information in connection with providing a specified service or performing a function on behalf of a covered entity. Although we are not directly subject to HIPAA, we could be subject to criminal penalties if we knowingly receive individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA. Further at the federal level, the Federal Trade Commission (“FTC”) also sets expectations for failing to take appropriate steps to keep consumers’ personal information secure, or failing to provide a level of security commensurate to promises made to individual about the security of their personal information (such as in a privacy notice) may constitute unfair or deceptive acts or practices in violation of Section 5 (a) of the Federal Trade Commission Act (“FTC Act”). The FTC expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. With respect to privacy, the FTC also sets expectations that companies honor the privacy promises made to individuals about how the company handles consumers’ personal information; any failure to honor promises, such as the statements made in a privacy policy or on a website, may also constitute unfair or deceptive acts or practices in violation of the FTC Act. While we do not intend to engage in unfair or deceptive acts or practices, the FTC has the power to enforce promises as it interprets them, and events that we cannot fully control, such as data breaches, may result in FTC enforcement. Enforcement by the FTC under the FTC Act can result in civil penalties or enforcement actions. EU Member States and other jurisdictions where we operate have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the General Data Protection Regulation (GDPR) imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. Switzerland has adopted laws that impose restrictions and obligations similar to the GDPR. The obligations and restrictions under the GDPR and Switzerland’s laws concern, in particular, in some instances the consent of the individuals to whom the personal data relate, the processing details disclosed to the individuals, the sharing of personal data with third parties, the transfer of personal data out of the ~~European Economic Area (EEA)~~ or Switzerland, contracting requirements (such as with clinical trial sites and vendors), and security breach notifications, as well as substantial potential fines, in some cases up to 4 % of annual global turnover, for breaches of the data protection obligations. Data protection authorities from the different EU Member States and the EEA may interpret the GDPR and applicable related national laws differently which could effectively result in requirements additional to those currently understood to apply under the GDPR. In addition, guidance on implementation and compliance practices may be updated or otherwise revised, which adds to the complexity of processing personal data in the EU. When processing personal data of subjects in the EU, we have to comply with applicable data protection and electronic communications laws. In particular, as we rely on service providers

processing personal data of subjects in the EU, we have to enter into suitable contract terms with such providers and receive sufficient guarantees that such providers meet the requirements of the applicable data protection laws, particularly the GDPR which imposes specific and relevant obligations. Enforcement by EU and ~~UK~~ **U. K.** regulators is active, and failure to comply with the GDPR or applicable Member State law may result in substantial fines. Legal mechanisms to allow for the transfer of personal data from the EEA or ~~UK~~ **U. K.** to the US may impact our ability to transfer personal data or otherwise may cause us to incur significant costs to do so legally. On July 16, 2020, the European Court of Justice ruled that the Privacy Shield is an invalid data transfer mechanism and confirmed that the Standard Contractual Clauses (**“SCCs”**) remain valid. If companies are relying on the SCCs as their transfer mechanism to transfer personal information from the EEA to the US (or to other jurisdictions not recognized as adequate by the EU), they must be incorporated into new and existing agreements within prescribed timeframes. The ~~UK~~ **U. K.** adopted versions of their own SCCs. Updating agreements to incorporate these new SCCs for the EEA and ~~UK~~ **U. K.** may require significant time and resources to implement, including through adjusting our operations, conducting requisite data transfer assessments, and revising our contracts. Companies that have not taken steps to demonstrate that their SCCs and personal data recipients in the US or other non-adequate jurisdictions are suitable to receive the personal data may be subject to enforcement actions by competent authorities in the EU for failure to comply with related data privacy rules. Additionally, the European Commission adopted a draft adequacy decision for the EU- US Data Privacy Framework, which reflects the assessment by the European Commission of the US legal framework. The draft decision concludes that the ~~United States~~ **U. S.** ensures an adequate level of protection for personal data transferred from the EU to US companies. After an approval ~~30process~~ **process**, the European Commission is expected to adopt the final adequacy decision, which will allow data to flow freely from the EU to the U. S. If we or our distributors fail to comply with applicable data privacy laws concerning, or if the legal mechanisms we or our distributors rely upon to allow, the transfer of personal data from the EEA or Switzerland to the US (or other countries not considered by the European Commission to provide an adequate level of data protection) are not considered adequate, we could be subject to government enforcement actions, including an order to stop transferring the personal data outside of the EEA and ~~significant~~ **significant** penalties against us. Moreover, our business could be adversely impacted if our ability to transfer personal data out of the EEA or Switzerland to the US is restricted, which could adversely impact our operating results. Failure to comply with data protection laws and regulations could result in unfavorable outcomes, including increased compliance costs, delays or impediments in the development of new products, increased operating costs, diversion of management time and attention, government enforcement actions and create liability for us (which could include civil, administrative, and / or criminal penalties), private litigation and / or adverse publicity that could negatively affect our operating results and business. Risks Related to Intellectual Property and Other Legal Matters We may be adversely affected by the expiration of patents that protect key aspects of ~~ILUVIEN~~ **our products** in the near- to medium- term. The patent rights relating to ILUVIEN ~~and YUTIQ~~ **and YUTIQ** licensed to us from EyePoint include one U. S. patent that will expire in August 2027, ~~two European patents that expired in April 2021 and will expire in the EU in October 2024, respectively, and counterpart filings to these patents although extensions have been obtained or applied for through May 2027 in various EU countries a number of other jurisdictions.~~ ~~No~~ **Otherwise, no** patent term extension will be available for any of these U. S. patents, European patents or any of our licensed U. S. or European pending patent applications. After these patents expire in August 2027 in the U. S. and October 2024 in Europe, we will not be able to block others from marketing FAC in an implant similar to ILUVIEN ~~or YUTIQ~~ **or YUTIQ**. We rely on patent, trademark and other intellectual property protection in the discovery, development, manufacturing and sale of our products. In particular, patent protection is, in the aggregate, important in our marketing of pharmaceutical products in the ~~United States~~ **U. S.** and most major markets outside of the ~~United States~~ **U. S.** Patents covering our products normally provide market exclusivity, which is important for the profitability of many of our products. As patents for certain of our products expire, we will or could face competition from lower priced generic or biosimilar products. In general, the expiration or loss of patent protection for a product may allow market entry by substitute products that could significantly reduce sales for the original product in a short amount of time. If our competitive position is compromised because of generics, biosimilars or otherwise, it could have a material adverse effect on our business and results of operations. In addition, proposals emerge from time to time for legislation to further encourage the early and rapid approval of generic drugs or biosimilars. Any such proposals that are enacted into law could increase the negative effect of generic competition. If we fail to comply with our obligations in the agreements under which we license development or commercialization rights to products or technology from third parties, we could lose license rights that are material to our business. Our licenses are material to our business, and we may enter into additional licenses in the future. We hold a license from EyePoint to intellectual property relating to ILUVIEN pursuant to the New Collaboration Agreement. **Pursuant to the Product Rights Agreement with EyePoint Parent, we also have the commercialization rights to YUTIQ in the entire world, except Europe, the Middle East and Africa as we had previously licensed from EyePoint rights to certain products, which included YUTIQ (known as ILUVIEN in Europe, the Middle East and Africa) for the prevention of relapse in recurrent NIU- PS in those territories. The Product Rights Agreement also excludes any rights to YUTIQ for the treatment and prevention of chronic NIU- PS in China and certain other countries and regions in Asia, which rights are subject to a pre- existing exclusive license between EyePoint Parent and Ocumension.** Our ability to pursue the development and commercialization of ~~ILUVIEN~~ **our products** depends upon the continuation of our ~~license from agreements with~~ **EyePoint and EyePoint Parent**. The New Collaboration Agreement imposes various commercialization, milestone payment, royalty payments, insurance and other obligations on us, including the right by EyePoint to audit. If we fail to comply with these obligations, EyePoint may have the right to terminate the license. Our license rights to EyePoint’s proprietary insert technology utilized in ILUVIEN could revert to EyePoint in certain circumstances, including failure to cure contractual breaches and filing for bankruptcy protection. We have from time to time amended the New Collaboration Agreement, and we may again seek to do so in the future if the need arises. **On December 17, 2020, EyePoint entered into a royalty purchase agreement**

(the “ SWK Agreement ”) with SWK Funding, LLC (“ SWK ”). We believe that given the terms of the SWK Agreement, however, it could be more difficult for us to do so, because SWK must consent to any amendment that could reasonably be expected to adversely affect the amount of the royalty payments that EyePoint has sold to SWK. Similarly, if we were to be engaged in a dispute with EyePoint regarding its enforcement or termination by either party, SWK’s rights could complicate the resolution of any such dispute. If our license with EyePoint, or any other current or future material license agreement, were terminated, or if we were unable to amend the New Collaboration Agreement or resolve any dispute related to such agreement, we may be unable to market the applicable products, such as ILUVIEN, that may be covered by such license, which would materially and adversely affect our business, results of operations and future prospects. ~~31We~~ **32We** do not control the commercialization of ILUVIEN in China, East Asia and the Western Pacific, and receipt of the value we currently anticipate will depend on, among other factors, Ocumension’s ability to further commercialize ILUVIEN in that region. We have granted an exclusive license to Ocumension ~~Therapeutics (Ocumension)~~ for the development and commercialization of our 0.19mg FAc intravitreal injection in China, East Asia and the Western Pacific. Our ability to receive aggregated potential sales milestone payments of up to \$ 89.0 million depend upon achievement by Ocumension of specified amounts of net sales of ILUVIEN in that region in the future. However, we cannot assure you as to the amount, if any, we might receive. If there are any adverse developments or perceived adverse developments with respect to Ocumension’s ability to commercialize ILUVIEN in China, East Asia and the Western Pacific, we may not realize the value we currently anticipate from this license, which would harm our business and may cause the price of our securities to fall. Examples of such adverse developments include, but are not limited to: regulatory hurdles in China, including related to the ongoing COVID-19 pandemic or the geopolitical tensions between the U. S. and China; competition, whether from current competitors or new products developed by others in the future; claims relating to intellectual property; global economic conditions; disruptions in Ocumension’s business; disappointing or lower than expected sales of ILUVIEN; disputes between Ocumension and us; or Ocumension deciding to modify, delay or halt its development and commercialization of ILUVIEN. If our license with Ocumension were terminated, or if Ocumension is unable to sell our licensed product, we will not receive any milestone payments under our license agreement, and our future revenues may be materially lower than expected. If we or our licensors are unable to obtain and maintain protection for the intellectual property incorporated into our products, the value of our technology and products will be adversely affected. Our success depends largely on our ability or the ability of our licensors to obtain and maintain protection in the U. S. and other countries for the intellectual property incorporated into our products. The patent situation in the field of biotechnology and pharmaceuticals generally is highly uncertain and involves complex legal and scientific questions. We or our licensors may be unable to obtain additional issued patents relating to our technology. Our success will depend in part on the ability of our licensors to obtain, maintain (including making periodic filings and payments) and enforce patent protection for their intellectual property, in particular, those patents to which we have secured exclusive rights. Under our license with EyePoint, EyePoint controls the filing, prosecution and maintenance of all patents. Our licensors may not successfully prosecute or continue to prosecute the patent applications to which we are licensed. Even if patents are issued in respect of these patent applications, we or our licensors may fail to maintain these patents, may determine not to pursue litigation against entities that are infringing upon these patents, or may pursue such litigation less aggressively than we ordinarily would. Without protection for the intellectual property that we own or license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects. Moreover, FAc is an off-patent active ingredient that is commercially available in several forms, including the extended release ocular implant Retisert. Even if issued, patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection that we may have for our products. In addition, our patents and our licensors’ patents may not afford us protection against competitors with similar technology. Litigation or third-party claims of intellectual property infringement would require us to divert resources and may prevent or delay our commercialization of ~~ILUVIEN~~ **our current products** or the development or regulatory approval of other product candidates. ~~ILUVIEN~~ **Our current products** or any future products or product candidates may infringe upon other parties’ intellectual property rights that are protected by patents or patent applications. Third parties may now or in the future own or control these patents and patent applications in the U. S. and abroad. These third parties could bring claims against us or our collaborators that would cause us to incur substantial expenses or divert substantial employee resources from our business. If those claims are successful, we could be required to pay substantial damages or could be prevented from developing any future product candidates. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay manufacturing, sales, research or development of the product or product candidate that is the subject of the suit. Several issued and pending U. S. patents claiming methods and devices for the treatment of eye diseases, including through the use of steroids, implants and injections into the eye, purport to cover aspects of ~~ILUVIEN~~ **our products**. For example, one of our potential competitors holds issued and pending U. S. patents and a pending European patent application with claims covering injecting an ~~32ocular~~ **33ocular** implant into a patient’s eye similar to ~~the ILUVIEN~~ **our current products’** applicator. There is also an issued U. S. patent with claims covering implanting a steroidal anti-inflammatory agent to treat an inflammation-mediated condition of the eye. If these or any other patents were held by a court of competent jurisdiction to be valid and to cover aspects of ~~ILUVIEN~~ **our current products**, then the owners of such patents would be able to block our ability to commercialize ~~ILUVIEN~~ **our current products** unless and until we obtain a license under such patents (which license might require us to pay royalties or grant a cross-license to one or more patents that we own), until those patents expire or unless we are able to redesign our ~~product~~ **products** to avoid any such valid patents. As a result of patent infringement claims, or in order to avoid potential claims, we or our collaborators may choose to seek, or be required to seek, a license from ~~the a~~ **third** party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive,

which would give our competitors access to the same intellectual property. Ultimately, we could be forced to cease some aspect of our business operations, or be prevented from commercializing a product if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. This could harm our business significantly. There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference proceedings declared by the U. S. Patent and Trademark Office and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to our products and technology. The cost to us of any litigation or other proceeding, regardless of its merit, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings better than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Intellectual property litigation and other proceedings may, regardless of their merit, also absorb significant management time and employee resources. If our efforts to protect the proprietary nature of the intellectual property related to our products are inadequate, we may not be able to compete effectively in our markets. The strength of our patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. In addition to the rights we have licensed from EyePoint relating to ILUVIEN **and the rights we have licensed from EyePoint Parent relating to YUTIQ**, we rely upon intellectual property we own, including patents, patent applications and trade secrets. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be too narrow to prevent third parties from developing or designing around these patents. Moreover, it is possible that a third -party could successfully challenge the scope (i. e., whether a patent is infringed), validity and enforceability of our licensed patents before patent expiration and obtain approval to market a competitive product. Further, the patent applications that we license or have filed may fail to result in issued patents. Patent examiners have rejected some claims in pending patent applications that we have filed or licensed. We may need to amend these claims. Even after amendment, a patent may not be permitted to issue. Further, the existing or future patents to which we have rights based on our New Collaboration Agreement with EyePoint may be too narrow to prevent third parties from developing or designing around these patents. Additionally, we may lose our rights to the patents and patent applications we license in the event of a breach or termination of our license agreement with EyePoint. Manufacturers may also seek to obtain approval to sell a generic version ~~versions~~ of ~~ILUVIEN~~ **our products** before the expiration of the relevant licensed patents. If the sufficiency of the breadth or strength of protection provided by the patents we license with respect to ~~ILUVIEN~~ **our products** or the patents we pursue related to ~~ILUVIEN~~ **our products** or any future product candidate is threatened, it could dissuade companies from collaborating with us to commercialize ~~ILUVIEN~~ **our products** and develop any future product candidates. Further, if we encounter delays in our clinical trials for any future product candidate, the period during which we could market those product candidates under patent protection would be reduced. Third- party claims of intellectual property infringement may prevent or delay our commercialization efforts with respect to ~~ILUVIEN~~ **our current products** and our discovery, development or commercialization efforts with respect to any future product candidates. Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. Third parties may assert that we are employing their proprietary technology without authorization. In addition, at least several issued and pending U. S. patents claiming methods and devices for the treatment of eye diseases, including through the use of steroids, implants and injections into the eye, purport to cover aspects of ~~ILUVIEN~~ **our current products**. Although we are not currently aware of any litigation or other proceedings or third- party claims of intellectual property infringement related to ~~ILUVIEN~~ **our current products**, the pharmaceutical industry is characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may in the future allege that our activities infringe their patents or that we are employing their proprietary technology without authorization. We may not have identified all the patents, patent applications or published literature that could potentially affect our business either by blocking our ability to commercialize our products or product candidates, by preventing the patentability of one or more aspects of our products or those of our licensors or by covering the same or similar technologies that may affect our ability to market our product. We cannot predict whether we would be able to ~~obtain~~ **obtain** a license on commercially reasonable terms, if at all. Any inability to obtain such a license under the applicable patents on ~~commercially~~ **commercially** reasonable terms, or at all, may have a material adverse effect on our ability to commercialize ~~ILUVIEN~~ **our current products** or any future products or product candidates until such patents expire. In addition, third parties may obtain patents in the future and claim that use of ~~ILUVIEN~~ **our current products**, our technologies or future products or product candidates infringes upon these patents. Furthermore, parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further commercialize ~~ILUVIEN~~ **our current products** or develop and commercialize any future product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, obtain one or more licenses from third parties or pay royalties, or we may be enjoined from further commercializing ~~ILUVIEN~~ **our current products** or developing and commercializing any future product candidates or technologies. In addition, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of ~~ILUVIEN~~ **our current products** or any future product candidate, and we have done so from time to time. We may fail to obtain future licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be unable to further commercialize ~~ILUVIEN~~ **our current products** or develop and commercialize any future product candidates, which could harm our business significantly. We may become involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time -consuming and unsuccessful. Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time -consuming. In addition, in an infringement proceeding, a court may decide that a

patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not ~~issuing~~ **being issued**. Interference proceedings brought by the U. S. Patent and Trademark Office may be necessary to determine the priority of inventions with respect to our patents and patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the U. S. 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 this type of litigation. In addition, there could 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 have a substantial adverse effect on the price of our common stock. If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected. We rely on trade secret protection and confidentiality agreements to protect certain proprietary know-how that is not patentable, for processes for which patents are difficult to enforce and for any other elements of our development processes with respect to ~~HUVIEN~~ **our current products** that involve proprietary know-how, information and technology that is not covered by patent applications. Any involuntary disclosure or misappropriation by third parties of our confidential or proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. We seek to protect confidential or proprietary information in part by confidentiality agreements with our employees, consultants and third parties. While we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the U. S. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U. S. and abroad. If we are unable to protect or defend the intellectual property related to our technologies, we will not be able to establish or maintain a competitive advantage in our market. ~~Our 35~~ **Our** products may become subject to unauthorized sales through parallel import or diversion into unintended markets, resulting in lower sales in those markets. As interest in and demand for ~~HUVIEN~~ **our current products** grows, and we expand distribution into new markets, ~~HUVIEN~~ **our current products** may become subject to parallel importing or diversion into unintended markets. Under EU law, parallel imports of approved products from one ~~34 member~~ **member** country into another are expressly permitted and cannot be prohibited. Furthermore, as our distribution expands, the possibility may increase for diversion of ~~HUVIEN~~ **our current products** into unanticipated markets. Sales of ~~our~~ **our** product by other companies through parallel import or diversion may adversely affect our product revenue, business and results of operations. Product liability lawsuits could divert our resources, reduce the commercial potential of our products and result in substantial liabilities, which insurance may not cover. Our business exposes us to the risk of product liability claims, which is inherent in the manufacturing, testing and marketing of drugs and related products. We face an increased risk of product liability as we further commercialize ~~HUVIEN~~ **our current products**, especially in the U. S. If the use of ~~HUVIEN~~ **our current products** or one or more of our future products causes physical harm, we may be subject to costly and damaging product liability claims. We believe that we may be at a greater risk of product liability claims relative to other pharmaceutical companies because ~~HUVIEN is~~ **our current products are** inserted into the eye, and it is possible that we may be held liable for eye injuries of patients who receive ~~HUVIEN~~ **our products**. Any product liability lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forego further commercialization of ~~HUVIEN~~ **our current products** or one or more of our future products. Even if we are not held liable, product liability lawsuits could cause adverse publicity and decrease the demand for ~~HUVIEN~~ **our current products**, which could have a material adverse effect on our business, results or operations and financial condition. ~~We~~ **Through the date of this report we** have not had any material claims against us ~~through the date of this report~~ **through the date of this report**. Although we maintain product liability insurance covering our clinical trial activities and our product sales, our aggregate coverage limit under these insurance policies is limited to \$ 10 million in most jurisdictions, and while we believe this amount of insurance is sufficient to cover our product liability exposure, these limits may not be high enough to fully cover potential liabilities. ~~The~~ **These** insurance ~~policies~~ **provides** - ~~provide~~ worldwide coverage where allowed by law. As we generate product revenue in new countries, we intend to obtain compulsory coverage in those countries that require it. However, we may not be able to obtain or maintain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims. If we are unable to obtain insurance at acceptable cost or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may materially and adversely affect our business and financial position. These liabilities could prevent or interfere with our product development and commercialization efforts. Certain Risks of Owning Our Common ~~Stock~~ **Conversion of all of our Series B Convertible Preferred Stock** ~~Stock~~ **Our** is contingent upon stockholder approval. Pursuant to the listing rules of The Nasdaq Global Market (Nasdaq), until our stockholders approve the issuance of the common stock underlying our Series B Convertible Preferred Stock (the Series B Preferred Stock), the Series B Preferred Stock may not be converted if such conversion would cause (i) the aggregate number of shares of common stock that would be issued pursuant to the related securities purchase agreement and the transactions contemplated thereby to exceed 1,401,901 (19.99% of the voting power or

number of shares of common stock, issued and outstanding immediately prior to the execution of the purchase agreement), which number will be reduced, on a share-for-share basis, by the number of shares of common stock issued or issuable pursuant to any transactions that may be aggregated with the transactions contemplated by the related securities purchase agreement under applicable Nasdaq rules; or (ii) the aggregate number of shares of common stock that would be issued pursuant to such conversion, when aggregated with any shares of common stock then beneficially owned by the holder (or group of holders required to be aggregated) of such shares, would result in a "change of control" under applicable Nasdaq listing rules. We have agreed to file a proxy statement with the SEC for the purpose of having our stockholders vote on a proposal to approve such issuances. Our stockholders may reject such a proposal, which would result in the Series B Preferred Stock to continue to accrue dividends at a rate of 6% per annum, accrued daily. For more information about the Series B Preferred Stock, see Part II, ITEM 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations — Overview — Recent Developments". The Series B Preferred Stock ranks senior to our common stock with respect to payments upon liquidation, dividends, and distributions. The rights of the holders of the Series B Preferred Stock rank senior to the obligations to our common stockholders. Upon our liquidation, the holders of Series B Preferred Stock are entitled to receive \$ 1,000.00 per share plus all accumulated and unpaid dividends (the Liquidation Preference). Until the holders of Series B Preferred Stock receive their Liquidation Preference in full, no payment will be made on any junior shares, including shares of our common stock. Further, the holders of Series B Preferred Stock have the right to participate in any payment of dividends or other distributions made to the holders of common stock to the same extent as if they had converted such preferred shares. The existence of senior securities such as the Series B Preferred Stock could have an adverse effect on the value of our common stock. Holders of Series B Preferred Stock have rights that may restrict our ability to operate our business. Under the Certificate of Designation of the Series B Preferred Stock, we are subject to certain covenants that limit our ability to create new series of preferred stock, other than series junior to the S Series B Preferred Stock, and our ability to incur certain indebtedness. Such restrictions may have an adverse effect on our ability to operate our business while the Series B Preferred Stock is outstanding. Our common stockholders may experience significant dilution upon the issuance of common stock upon conversion of the Series B Preferred Stock or exercise of outstanding warrants to purchase common stock. The issuance of common stock upon conversion of some or all of the Series B Preferred Stock will dilute the ownership interests of existing holders of shares of our common stock. As of March 24, 2023, if all of the Series B Preferred Stock were converted and all of our outstanding warrants to purchase common stock were exercised in full, we would have issued 11,428,572 shares of common stock (without giving effect to any limitation on conversions or exercise). The number of shares of common stock issuable upon conversion of the Series B Preferred Stock will increase as dividends continue to accrue on such shares at a rate of 6% per annum, accrued daily. The conversion price of the Series B Preferred Stock and the exercise price of the warrants to purchase common stock are subject to certain customary adjustments, including a weighted average anti-dilution adjustment (which will remain in effect until the Series B Preferred Stock converts). If stockholder approval is obtained, the Series B Preferred Stock will automatically be converted into shares of common stock and the exercise price of the warrants will no longer be subject to a weighted average anti-dilution adjustment. The Series B Preferred Stock contains covenants and other terms that may limit our business flexibility and affect the market price of our common stock. For so long as at least 20% of the shares of Series B Preferred Stock are held by the initial investors or their affiliates, we may not, without first obtaining the approval of the holders of at least a majority of the then-outstanding shares of Series B Preferred Stock: • amend the Certificate of Designation of the Series B Preferred Stock; • amend our certificate of incorporation (including by filing any new certificate of designation or elimination) or our bylaws, in a manner that adversely affects the rights, preference or privileges of the Series B Preferred Stock; • increase or decrease the authorized number of shares of Series B Preferred Stock or issue additional shares of Series B Preferred Stock, other than to the investors; • authorize, create, issue or obligate us to issue (by reclassification, merger or otherwise) any security (or any class or series thereof) or any indebtedness, in each case that has any rights, preferences or privileges senior to, or on a parity with, the Series B Preferred Stock, or any security convertible into or exercisable for any such security or indebtedness, subject to certain exceptions; • redeem, purchase or otherwise acquire (or pay into or set aside for a sinking fund for such purpose) any shares of capital stock, subject to certain exceptions; • declare or pay any dividend or distribution on any shares of capital stock; provided, however, that this restriction shall not apply to dividends payable to holders of common stock that consist solely of shares of common stock for which adjustment to the conversion price of the Series B Preferred Stock is made pursuant to the Certificate of Designation of the Series B Preferred Stock; or • incur any indebtedness in excess of \$ 5,000,000 or any secured indebtedness other than as permitted by the Certificate of Designation of the Series B Preferred Stock. There is no guarantee that the holders of the Series B Preferred Stock would approve any such restricted action, even where such an action would be in the best interests of our stockholders. Any failure to obtain such approval could harm our business and result in a decrease in the value of our common stock. Our failure to meet the continued listing requirements of The Nasdaq Global Market could result in a delisting of our common stock and make it harder for shareholders to trade in our common stock. Our common stock is listed on Nasdaq, which imposes, among other requirements, a minimum bid price requirement and a minimum market value requirement. In 2019 we failed on three occasions to meet the standards for continued listing on Nasdaq. If the closing bid price for our common stock is less than \$ 1.00 per share for 30 consecutive business days or the total market value of our publicly held shares closes at less than \$ 15 million for 30 consecutive business days, Nasdaq may send us a notice stating we will be provided a period of 180 days to regain compliance with these requirements or else Nasdaq may make a determination to delist our common stock. On March 23, 2023, we received a notice (the "MVPHS Notice") from Nasdaq, stating that our listed securities failed to comply with the \$ 15 million market value of publicly held shares (Market Value of Publicly Held Shares) requirement for continued listing on The Nasdaq Global Market in accordance with Nasdaq Listing Rule 5450 (b) (2) (C) based on our Market Value of Publicly Held Shares for the 30 consecutive business days prior to the date of the MVPHS Notice. 36 In accordance with Nasdaq Listing Rule 5810 (c) (3) (D), we were have been provided a period of 180 calendar days from the

date of the MVPHS Notice, or until September 19, 2023, in which to regain compliance (the “Compliance Period”). **Although we In order to regain regained** compliance **within**, our Market Value of Publicly Held Shares must close at \$ 15.0 million or more for a minimum of ten consecutive trading days during the Compliance Period **on June 7**. We intend to consider our available options to resolve this noncompliance, but **2023 by qualifying under the equity standard under Nasdaq Listing Rule 5450 (b) (1) (C) as a result of our Series B preferred stock financing**, there can be no assurance that we will be able to **regain-maintain** compliance with the Market Value of Publicly Held Shares requirement or **maintain compliance with** other Nasdaq listing requirements **in**. In the event that we do not regain compliance within the Compliance Period, we may be eligible to transfer to The Nasdaq Capital Market before the expiry of the Compliance Period. However, if it appears to Nasdaq that we will not be able to cure the deficiency, or if we are not otherwise eligible, Nasdaq will provide notice to us that our common stock will be subject to delisting. In the event of such notification, we may appeal Nasdaq’s determination to delist its securities, but there-- **the future** can be no assurance Nasdaq would grant our request for continued listing. The delisting of our common stock from Nasdaq may make it more difficult for us to raise capital on favorable terms in the future. Such a delisting would likely have a negative effect on the price of our common stock and would impair our stockholders’ ability to sell or purchase our common stock when they wish to do so. Further, if we were to be delisted from Nasdaq, our common stock would cease to be recognized as covered securities and we would be subject to regulation in each state in which we offer our securities. Even if we regain compliance, there is no assurance that any actions that we take to restore our **compliance-36compliance** with Nasdaq’s listing requirements would stabilize the market price or improve the liquidity of our common stock, prevent our common stock from remaining below the Market Value of Publicly Held Shares required for continued listing or prevent future non-compliance with Nasdaq’s listing requirements. Delisting may also result in our common stock trading on the over-the-counter market, which may be a less liquid market. In such **a** case, our stockholders’ ability to trade, or obtain quotations of the market value of, shares of our common stock would be severely limited because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask prices for our securities. In addition to the foregoing, if our common stock is delisted from Nasdaq and it trades on the over-the-counter market, the application of the “penny stock” rules could adversely affect the market price of our common stock and increase the transaction costs to sell those shares. The SEC has adopted regulations which generally define a “penny stock” as an equity security that has a market price of less than \$ 5.00 per share, subject to specific exemptions. ~~The last reported trade of our common stock on The Nasdaq Global Market was at a price below \$ 5.00 per share.~~ If our common stock is delisted from Nasdaq and it trades on the over-the-counter market at a price of less than \$ 5.00 per share, our common stock would be considered a penny stock. The SEC’s penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document that provides information about penny stocks and the risks in the penny stock market. The broker-dealer must also provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and the salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer’s account. In addition, the penny stock rules generally require that before a transaction in a penny stock occurs, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser’s agreement to the transaction. If applicable in the future, these rules may restrict the ability of brokers-dealers to sell our common stock and may affect the ability of investors to sell their shares, until our common stock no longer is considered a penny stock. As long as we remain subject to the rules of Nasdaq, we will be unable to access equity capital without stockholder approval if such equity capital sales would result in an equity issuance above regulatory thresholds and consequently, we may be unable to obtain financing sufficient to sustain our business if we are unsuccessful in soliciting requisite stockholder approvals. Our ability to access equity capital is subject to Nasdaq Listing Rule 5653 (d), commonly referred to as the Nasdaq 20 % Rule, which requires stockholder approval of a transaction other than a public offering involving the sale, issuance, or potential issuance by a company of common stock (or securities convertible into or exercisable for common stock) equal to 20 % or more of the common stock, or 20 % or more of the voting power outstanding before the issuance for less than the greater of book or market value of the shares. The operation of the Nasdaq 20 % Rule could limit our ability to raise capital through issuance of common stock or convertible securities without jeopardizing our listing status. If we were to violate the Nasdaq 20 % Rule, our common stock would be subject to delisting from Nasdaq and share prices and trading volumes would likely suffer. Our stock price has been and may continue to be volatile, and the value of an investment in our common stock may decline. The realization of any of the risks described in these risk factors or other unforeseen risks could have a dramatic and adverse effect on the market price of our common stock. The trading price of our common stock has from time to time been and may in the future be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including those discussed in this “Risk Factors” section. From time to time, we estimate the timing of the accomplishment of various regulatory, scientific, clinical and other product development goals or milestones. These milestones may include: **37** • the submission of regulatory filings, • the notification of the results of regulatory filings, • the anticipated commercial launch of **ILUVIEN-our products** in various new jurisdictions or for new or expanded indications, • any future products or product candidates and • the commencement or completion of scientific studies and clinical trials. Also, from time to time, we publicly announce the anticipated timing of some of these milestones. All of these milestones are based on a variety of assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, our stock price may decline and the further commercialization of **ILUVIEN-our current products** or any future products or product candidates may be delayed. In addition, the stock market has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of publicly traded companies, including us. Broad market and industry factors may seriously affect the market price of companies’ stock, including ours, regardless of actual operating performance. These fluctuations may be even more pronounced in the trading market for our

stock. In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities class action litigation has often ~~been~~ **been** initiated against these companies. This litigation, if brought against us, could result in substantial costs and a diversion of our management's attention and resources. Significant sales of our common stock could depress or reduce the market price of our common stock, cause our shares of common stock to trade below the prices at which they would otherwise trade, or impede our ability to raise future capital. A small number of institutional investors and private equity funds hold a significant number of shares of our common stock ~~and all of our shares of Series B Preferred Stock~~. Sales by these stockholders of a substantial number of common shares, or the expectation of such sales, could cause a significant reduction in the market price of our common stock. We may sell securities in the future, if we determine it is appropriate or necessary to do so, which could cause a significant reduction in the market price of our common stock. In addition to our outstanding common stock, as of December 31, ~~2022~~ **2023**, options to purchase ~~1,317,046~~ **339,195** shares of our common stock were outstanding. Upon the exercise of the stock options in accordance with their terms, the shares so acquired may be resold freely, subject to restrictions imposed on our affiliates under the SEC's Rule 144 and to our securities trading policy. Additionally, Ocumension holds 1,144,945 shares of our common stock, and the lock-up restrictions on those shares have expired. ~~Moreover, as of March 24, 2023, if all of our outstanding Series B Preferred Stock were converted and all of our outstanding warrants to purchase common stock were exercised in full, we would have issued 11,428,572 shares of common stock (without giving effect to any limitation on conversions or exercise).~~ If significant sales of our common stock occur in short periods, this could reduce the market price of our common stock. Any reduction in the trading price of our common stock could impede our ability to raise capital on attractive terms. Actual or perceived significant sales of our common stock could depress or reduce the market price of our common stock, cause our shares of common stock to trade below the prices at which they would otherwise trade or impede our ability to raise future capital. Future sales and issuances of our equity securities or rights to purchase our equity securities, including pursuant to our equity incentive plans, would result in dilution of the percentage ownership of our stockholders and could cause our stock price to fall. To the extent we raise additional capital by issuing equity securities; our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, whether in public or private offerings, investors may be diluted by subsequent sales. Those sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to existing stockholders. ~~In addition, the Series B Preferred Stock is entitled to price-based anti-dilution protection in connection with certain financings, which has the potential to further dilute our other stockholders.~~ Pursuant to the ~~2019~~ **2023** Omnibus Incentive Plan, our board of directors is authorized to grant various types of equity-based awards, including stock options ~~and~~, **restricted stock units ("RSUs") and performance stock units ("PSUs")**, to our employees, directors and consultants. As of December 31, ~~2022~~ **2023**, a total of ~~754,142~~ **933,511** shares of our common stock were available for issuance under new awards granted under our 2019 Omnibus Incentive Plan. ~~38~~ **Subsequent to year end, we adopted the 2024 Equity Inducement Plan on February 8, 2024 under which our board of directors is authorized to grant inducement awards, including stock options, RSUs and PSUs, to our employees and directors of up to 800,000 common shares.** We do not intend to pay dividends on our common stock and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock. We have never declared or paid any cash dividend on our common stock and do not currently intend to do so for the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. ~~Further~~ **Furthermore**, the rights and preferences of ~~our Series B Preferred Stock and~~ our 2019 Loan Agreement also place limitations on our ability to declare or pay any dividend or distribution on any shares of capital stock. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in their value. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares. Anti-takeover provisions in our charter and bylaws and in Delaware law could prevent or delay acquisition bids for us that stockholders might consider favorable and could entrench current management. We are a Delaware corporation. The anti-takeover provisions of the Delaware General Corporation Law may deter, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change in control would be beneficial to our existing stockholders. In addition, our restated certificate of incorporation and bylaws may discourage, delay or prevent a change in our management or control over us that stockholders may consider favorable. Our restated certificate of incorporation and bylaws: **38** • authorize the issuance of "blank check" preferred stock that could be issued by our Board of Directors to thwart a takeover attempt; • do not provide for cumulative voting in the election of directors, which would allow holders of less than a majority of our outstanding common stock to elect some directors; • establish a classified Board of Directors, as a result of which the successors to the directors whose terms have expired will be elected to serve from the time of election and qualification until the third annual meeting following their election; • require that directors only be removed from office for cause; • provide that vacancies on the Board of Directors, including newly created directorships, may be filled only by a majority vote of directors then in office; • contain certain protective provisions in favor of the holders of Series A Convertible Preferred Stock; • limit who may call special meetings of stockholders; • prohibit common stockholder action by written consent, requiring all actions of the holders of common stock to be taken at a meeting of the stockholders; and • establish advance notice requirements for nominating candidates for election to the Board of Directors or for proposing matters that can be acted upon by stockholders at stockholder meetings. If securities or industry analysts do not publish research or reports or publish unfavorable research or reports about our business, our stock price and trading volume could decline. The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. If one or more of the analysts who ~~covers~~ **cover** us downgrades our stock, our stock

price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline. We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to comply with various securities laws and regulations and Nasdaq listing requirements. As a public company, we incur significant accounting, legal and other expenses. The Sarbanes- Oxley Act of 2002, as well as rules subsequently implemented by the SEC and Nasdaq, has imposed various requirements on public companies, including requiring establishment and maintenance of effective disclosure controls and procedures, internal controls over financial reporting, and changes in corporate governance practices. Our management and other personnel are required to devote a substantial amount of time and expense to legal compliance. In addition, changing laws, regulations, and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs, and making some activities more time-consuming. We intend to continue investing in substantial resources to comply with evolving laws, regulations, and standards, and this investment may result in increased expenses and a diversion of management's time and attention from business operations to compliance activities. For example, U. S. and international regulators, investors and other stakeholders are increasingly focused on environmental, social, and governance ("ESG ") matters. New domestic and international laws and regulations relating to ESG matters, including climate change, cybersecurity, human capital, diversity and sustainability, are under consideration or being adopted, which may include specific, target- driven disclosure requirements or other obligations. Our compliance with such laws and regulations will require additional investments and implementation of new practices and reporting processes, all entailing additional compliance risk. If our efforts to comply with new or existing laws, regulations, and standards differ from the activities ~~39intended~~ **intended** by regulatory or governing bodies for any reason, regulatory authorities may initiate legal proceedings against us, our business may be harmed and the market price of our common stock could decline. We are a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to smaller reporting companies will make our common stock less attractive to investors. We are a smaller reporting company under Rule 12b- 2 of the Securities Exchange Act of 1934. For as long as we continue to be a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on smaller reporting company exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile. **ITEM 39 ITEM 1B. UNRESOLVED STAFF COMMENTS** None. **ITEM 2-1C. PROPERTIES**

CYBERSECURITY Risk Management and Strategy: The Company has processes for assessing, identifying, and managing material risks from cybersecurity threats. The Company has designed and implemented a Security Incident Response Plan for cybersecurity incidents and related processes which are overseen by management and cybersecurity professionals. Cybersecurity threats are identified and escalated to a Security Incident Response Team or member thereof pursuant to criteria set forth in these processes. These processes also include overseeing and identifying risks from cybersecurity threats associated with the use of third- party service providers, if any. Our cybersecurity policies, standards, processes, and practices are integrated into the Company's overall risk management and compliance program and are overseen by the Audit Committee. The Compliance Committee, led by our Chief Compliance Officer (" CCO ") and the IT Committee, led by our Chief Financial Officer (" CFO ") are responsible for establishing and monitoring the integrity and effectiveness of controls and other procedures. In general, we seek to address cybersecurity risks through a cross- functional approach focused on preserving the security and availability of information that we collect and store by identifying, preventing, and mitigating cybersecurity threats and effectively responding to cybersecurity incidents when they occur. U. S. segment The Company also engages consultants, our U- auditors, and other third parties in connection with these processes to assist in the design of cybersecurity measures and employee training and to test the effectiveness of the Company's processes and measures. S- headquarters Governance: [?] Board of Directors The Board's oversight of cybersecurity risk management is located in Alpharetta, Georgia, consisting of approximately 14, 900 square feet of office space. Our lease for this facility expires in December 2032. information technology and our CCO, as well as other members of management. The Audit Committee receives presentations and reports on cybersecurity risks, which address a wide range of topics including recent developments, evolving standards, vulnerability assessments, the threat environment, technological trends and information security considerations arising with respect to our peers and third parties. The board of directors and the Audit Committee also receive prompt and timely information regarding any cybersecurity incident, we as well as ongoing updates regarding any such incident until it has been addressed. On a periodic basis, the board of directors, through the Audit Committee, discuss our approach to cybersecurity risk management with the CFO and CCO. The Audit Committee is informed of material risks, if any, from cybersecurity threats pursuant to Company policies, and at least once per quarter the Company's CCO reports to the Audit Committee generally on cybersecurity matters. approximately 4, 500 square feet of office space in Dublin, Ireland, approximately 1, 000 square feet of office space in Berlin, Germany, and approximately 6 material risks, if any 000 square feet of office space in Aldershot, U- from cybersecurity threats. K- [?] Management The Company's management, including members of its IT and Compliance Committees, also assess and manage material risks, if any, from cybersecurity threats with the assistance of our third- party IT and cybersecurity vendors. Our leases Collaborative Approach: We have implemented a comprehensive, cross- functional approach to identifying, preventing, and mitigating cybersecurity threats and incidents, while also implementing controls and procedures that provide for these-- the prompt escalation of certain cybersecurity incidents so facilities in Ireland and Germany expire in August 2024 and June 2024,

respectively. Our lease for the U. K. facility expires in December 2024. We anticipate that **decisions regarding** following the expiration of these **the public disclosure** leases, we will be able to lease additional or alternative space at commercially reasonable terms. Additionally, we have an **and reporting** agreement to use approximately 400 square feet of **such incidents** office space in Lisbon, Portugal, which can be terminated with 90 days' notice **made by management in a timely manner**.

Technical Safeguards: We **deploy technical safeguards that are designed to protect our information systems** do not own any real estate. ~~ITEM 3. LEGAL PROCEEDINGS From~~ **from cybersecurity threats** time to time, **including firewalls** we may become subject to legal proceedings, claims, **intrusion prevention** and litigation arising in the ordinary course of business **detection systems, anti-malware functionality, and access controls, which are evaluated and improved through vulnerability assessments and cybersecurity threat intelligence**.

Incident Response and Recovery Planning: We currently are **committed** not a party to any threatened **establishing and maintaining comprehensive incident response and recovery plans to address or our response to a cybersecurity incident** pending material litigation and do not have contingency reserves established for any litigation liabilities. However, **Third-Party Risk Management: We maintain a risk-based approach to identifying and overseeing cybersecurity risks presented by** third parties might allege that we are infringing their patent rights or that we are otherwise violating their intellectual property rights, including trade names **vendors, service providers** and trademarks. Such **other external users of our systems, as well as the systems of** third parties may resort to litigation. We accrue contingent liabilities when it is probable that future expenditures will be made and such expenditures can be reasonably estimated **could adversely impact our business in the event of a cybersecurity incident affecting those third-party systems**.

~~ITEM 4. MINE SAFETY DISCLOSURES Not applicable.~~