

Risk Factors Comparison 2025-02-25 to 2024-02-23 Form: 10-K

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

Risks Related to Our Business • Failure to achieve commercial success of iDose TR could materially impact our business. • Downturns or volatility in general economic conditions and public health crises could harm our business. • Supply and / or manufacturing disruptions impacting our principal revenue-producing products could reduce our gross margins and negatively impact our operating results. • We may not reach sustained profitability. • We may fail to generate sufficient sales of our commercialized products or to develop and commercialize additional products. • We are subject to a variety of risks associated with our international operations. • We may not meet our customers' expectations for the quality or delivery of our products, which could harm our reputation and sales. • If ophthalmic surgeons do not use or if they misuse our products, our business could be harmed. • We may fail to manage our anticipated growth effectively and may not be able to meet customer demand. • We may be unable to retain or recruit qualified personnel for growth. • We have and may continue to enter into acquisitions, collaborations, in-licensing agreements, joint ventures, alliances or partnerships with third parties that could fail. • Cybersecurity incidents, service interruptions, or data corruption could materially disrupt our operations and adversely affect our business. • Failure to comply with data privacy and security laws could have a material adverse effect on our business. • Our net operating loss tax carryforwards may not be available, **or may be subject to certain limitations**, to offset future taxable income.

Risks Related to Our Indebtedness • ~~Our~~ **If we incur future indebtedness, our** debt service obligations could limit our cash flow, and ~~we may not have sufficient cash flow from our business to pay our debt obligations.~~ • ~~The conditional conversion feature of the Convertible Notes, if triggered,~~ may adversely affect our financial condition and operating results. • ~~We may fail to raise the funds necessary to settle conversions of the Convertible Notes in cash or to repurchase the Convertible Notes upon a fundamental change.~~ • The capped call transactions may affect the value of our common stock, **par value \$ 0.001 per share (Common Stock)** and subject us to counterparty risk.

Risks Related to Our Regulatory Environment • **Healthcare legislative reform measures and changes in U. S. and international trade policies may have a material adverse effect on our business and results of operations.** • Compliance with applicable regulations can be costly and failure to comply with such regulations could harm our business, financial condition and operating results. • Legislative or regulatory reform of the healthcare system could hinder or prevent our products' commercial success. • Inadequate or inconsistent reimbursement for our products may adversely impact our business.

Risks Related to Our Intellectual Property • Failure to protect our intellectual property could substantially impair our ability to compete. • Intellectual property claims or litigation could be costly, time-consuming and unsuccessful and could interfere with our ability to successfully commercialize our products.

Risks Related to Our Common Stock • Provisions in our Certificate of Incorporation and Bylaws limit the ability of stockholders to take certain actions and could delay or discourage takeover attempts. • Our Certificate of Incorporation designates the sole and exclusive forum for certain types of actions and proceedings, which could limit our stockholders' ability to obtain a favorable judicial forum. ~~2PART-~~ **PART** ITEM 1. BUSINESS Overview Glaukos is an ophthalmic pharmaceutical and medical technology company focused on developing novel, dropless therapies and commercializing associated products for the treatment of glaucoma, corneal disorders, and retinal disease. We first developed Micro-Invasive Glaucoma Surgery (MIGS) as an alternative to the traditional glaucoma treatment paradigm, launching our first MIGS device commercially in 2012. **In 2024, we commenced commercialization activities for iDose® TR, a first-of-its-kind, long-duration, intracameral procedural pharmaceutical implant designed to continuously deliver glaucoma drug therapy inside the eye for extended periods of time.** We also offer commercially a proprietary bio-activated pharmaceutical therapy for the treatment of a rare corneal disorder, keratoconus, that was approved by the United States (U. S.) Food and Drug Administration (FDA) in 2016. **We are Beyond our approved products, we continue to develop and advance a portfolio of novel, dropless platforms—platform technologies designed to support ongoing pharmaceutical—meaningfully advance the standard of care and improve outcomes medical device innovations. Products and product candidates for patients suffering from chronic** each of these platforms are designed to advance the standard of care through better treatment options across the areas of glaucoma, corneal disorders such as keratoconus, dry-eye and refractive vision correction, and retinal diseases such as neovascular age-related macular degeneration (AMD), diabetic macular edema (DME), and retinal vein occlusion (RVO). Ophthalmic diseases and disorders are a national and global health concern and, as the population ages, the number of individuals with vision impairment and blindness is increasing. Moreover, improving access to cost-effective tools is increasing the diagnosis of sight-threatening ocular diseases globally and driving demand for innovative products, technologies, and therapies that improve clinical outcomes, demonstrate favorable safety profiles and provide ease of use and reliability. In response to the significant unmet needs that exist within ophthalmology we have designed commercial and development-stage solutions to provide ophthalmologists and other eye care professionals with various treatment options. Our commercial solutions and development-stage product candidates include: • **procedural pharmaceuticals based on an intracameral drug delivery technology designed to reduce IOP by delivering therapeutic levels of glaucoma medication from inside the eye over an extended period of time;** • MIGS products that primarily involve the insertion of a micro-scale device designed to reduce intraocular pressure (IOP) by restoring the natural aqueous humor outflow pathways for patients suffering from glaucoma; • ~~procedural pharmaceuticals based on an intracameral drug delivery technology designed to reduce IOP by delivering therapeutic levels of glaucoma medication from inside the eye over an extended period of time;~~ • bio-activated pharmaceuticals that are intended to strengthen, stabilize, and reshape the cornea for patients impacted by corneal ectatic disorders such as keratoconus or refractive disorders; • transdermal pharmaceuticals that are applied to the eyelid and designed to treat glaucoma, dry eye,

presbyopia, demodex blepharitis, and other ocular surface diseases and disorders; and • proprietary micro- invasive, bio-erodible posterior sustained release drug delivery implants that are designed to elute pharmaceuticals over time to improve the vision of patients impacted by retinal diseases such as age-related macular degeneration (AMD), diabetic macular edema (DME), and retinal vein occlusion (RVO).

Recent Developments On December 13, 2023, we received FDA approval for iDose TR indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. iDose TR is an intracameral procedural pharmaceutical therapy designed to continuously deliver 24/7 therapeutic levels of a proprietary formulation of travoprost inside the eye for extended periods of time. On October 16, 2023, we entered into an Exclusive License Agreement (Stuart License Agreement) with Stuart Therapeutics, Inc. (Stuart), pursuant to which Stuart granted us an exclusive, worldwide license to develop and commercialize products incorporating certain of its owned or controlled technologies, including its ST-113 drug compound, that may be utilized to provide neuroprotection in glaucoma. Pursuant to the terms of the Stuart License Agreement, we made a one-time upfront payment of \$2.0 million to Stuart, and may have ongoing milestone payments based on the success of the development and regulatory approval of the proprietary technologies. If these proprietary technologies are commercialized, we may also have single digit royalty payment and commercial milestone obligations that are determined based upon annual net sales thresholds. On July 17, 2023, we entered into a collaboration and marketing agreement (Collaboration and Marketing Agreement) with Radius XR, Inc. (Radius), in which we became the exclusive sales agent to market, promote and solicit orders for the Radius XR™ wearable patient engagement and diagnostic system within the United States. Pursuant to the Collaboration and Marketing Agreement, we earn commission payments based on sales of Radius products resulting from our marketing and promotion efforts. In connection with the Collaboration and Marketing Agreement, we entered into a convertible promissory note (Convertible Promissory Note) pursuant to which we agreed to fund Radius up to \$5.0 million, based upon the occurrence of certain potential future events. The Convertible Promissory Note bears interest on the outstanding principal at the rate of 5.0% per annum, and the outstanding principal and interest is convertible into preferred stock or capital stock in Radius under certain circumstances. As of December 31, 2023, \$2.8 million is outstanding under the Convertible Promissory Notes. On May 16, 2023, we issued \$3.0 million of our common stock in connection with the acquisition of intellectual property rights regarding certain formulations and methods for treating an ophthalmic disorder, including all related patents and patent applications, technology and know-how. We accounted for the transaction as an asset acquisition as the set of acquired assets did not constitute a business. We may have ongoing milestone payments based on achieving certain clinical and regulatory milestones depending on the success of the development and approval of the proprietary technologies. Additionally, if these proprietary technologies are commercialized, we may also have royalty payment and commercial milestone obligations that are determined based upon annual net sales thresholds.

Products and Pipeline We operate in one operating segment and our primary business activity is the development and commercialization of therapies across several end markets within ophthalmology. In an effort to provide greater visibility into our business, the following discussion is presented based on our three-five principal end markets novel platforms that address four therapeutic areas within ophthalmology: glaucoma, rare corneal disorders and retinal diseases- disease, anterior segment and posterior segment.

Glaucoma Glaucoma is a group of eye diseases characterized by progressive, irreversible and largely asymptomatic vision loss in which elevated levels of IOP are often associated with optic nerve damage that can cause blindness. While some glaucoma patients do not experience an increase in IOP, it is widely considered a major risk factor in glaucoma's progression, and reduction in IOP is the only clinically proven treatment for the disease. Elevated IOP occurs when aqueous humor is not circulating normally or properly draining from the front part of the eye. We have three primary commercialized micro-scale surgical device products designed to treat glaucoma: the iStent, the iStent inject W, and the iStent infinite, collectively referred to as the "iStent family of products." The iStent and the iStent inject W are micro-bypass stents, approved by designed to treat mild-to-moderate open angle glaucoma through the restoration of the natural physiologic outflow pathways for U.S. Food and Drug Administration (FDA) that improve aqueous humor outflow and, These stents are inserted through the small corneal incision made during cataract surgery, and implanted in the trabecular meshwork of the eye are designed to treat mild-to-moderate open angle glaucoma. Our iStent, a single stent device which reduces IOP by restoring the natural physiologic pathways for aqueous humor, obtained U.S. FDA clearance in 2012 and was the first commercially available MIGS treatment solution. The iStent inject W device includes two stents pre-loaded in an auto-injection system designed to allow the surgeon to inject stents through a single corneal entry and was approved by the FDA in 2018. The iStent and iStent inject W procedures are currently reimbursed in the U.S. by Medicare and all major national private payors. Some or all of the iStent family of products are commercially available in numerous countries, including Australia, Brazil, Canada, Japan, certain members of the European Union members, the United Kingdom, Japan, Australia, Canada and Brazil a majority of the European Union (EU) members, and other countries, even though reimbursement may not always be available for all such procedures. In August 2022, we received FDA 510(k) clearance for the iStent infinite indicated for use in the treatment of patients with glaucoma uncontrolled by prior medical and surgical therapy. The iStent infinite product includes three heparin-coated titanium-titanium stents preloaded into an auto-injection system that allows the surgeon to inject stents across a span of up to approximately six clock hours around Schlemm's canal, the eye's primary drainage channel. Once in place, the stents are designed to lower IOP by restoring the natural, physiological outflow of aqueous humor. iStent infinite is our first FDA-cleared micro-bypass stent that can be used in either a standalone procedure or in conjunction with cataract surgery for glaucoma patients uncontrolled by prior medical and surgical therapy. We have also licensed from Santen Pharmaceutical Co., Ltd. (Santen) the PRESERFLO MicroShunt. The MicroShunt is an ab-externo device being developed for treatment of glaucoma where IOP is uncontrolled with maximum tolerated medical therapy or where progression of the disease warrants surgery. Santen submitted a Pre-Market approval (PMA) application to the FDA in June 2020. In April 2022, the U.S. FDA completed its review for the MicroShunt PMA submission and notified InnFocus, Inc, a Santen company,

of a Non- Approvable determination. We then assumed clinical development from Santen and now plan to commence a Phase 3 clinical trial for the PRESERFLO MicroShunt in 2025, which we believe would be the basis to support potential future FDA approval in the future. We have commercialized the PRESERFLO MicroShunt in various countries including, but not limited to, Australia, Canada and Brazil. iDose Sustained- Release Pharmaceuticals In December 2023, we received FDA approval for iDose TR, indicated for the reduction of IOP in patients with open- angle glaucoma or ocular hypertension. iDose TR is a first- of- its- kind, intracameral procedural pharmaceutical therapy designed to continuously deliver 24/7 therapeutic levels of a proprietary formulation of travoprost inside the eye for extended periods of time. iDose TR is intended to improve the standard of care by addressing the ubiquitous patient non- compliance issues and chronic side effects associated with topical glaucoma medications. PMA iDose TR was initially launched in a controlled manner during the first quarter of 2024. Up until the beginning of the third quarter of 2024, iDose TR was reimbursed with Medicare under a miscellaneous C- code, and the Company was in the process of securing both the establishment of a facility fee as well as a physician fee payment. On March 21, 2024, the U.S. Centers for Medicare & Medicaid Services (CMS) assigned application to the FDA in June 2020. In temporary Current Procedural Terminology (CPT) codes 0660T and 0661T which are designed to cover the facility fee payment to ambulatory payment classification 5492, effective April 1, 2022-2024, the U.S. FDA completed its review. Then, on April 2, 2024, CMS assigned a unique, permanent 4 Healthcare Common Procedure Coding System (HCPCS) J- code that covers reimbursement for the iDose TR product. This J- code became effective MicroShunt PMA submission and notified InnFocus, Inc, a Santen company, of a Non- on - Approvable determination July 1, 2024. We Lastly, for products like iDose TR that are currently covered by temporary CPT codes, the physician fee payment rates are set by the multi- state, regional contractors, or Medicare Administrative Contractors (MACs), that are responsible for administering Medicare claims. Throughout 2024, we have been continuously working with the FDA- MACs to evaluate streamline an and alternate pathway- obtain consistent reimbursement payments for iDose TR related to potential approval. As such the permanent J- code, timing of a potential approval and U.S. commercial launch is currently unknown. We have commercialized the facility fee, PreserFlo MicroShunt in Australia and the physician fee Canada beginning in 2021.

Corneal Disorders

The iLink Bio- Activated Pharmaceuticals

The cornea, the eye' s outermost layer, is a clear, dome- shaped surface that functions best as a lens when the cornea is strong and shaped properly. The cornea is responsible for the majority of the eye' s total focusing power and corneal disorders, including ectasia, refractive vision errors and dry eye, among others, can cause vision impairment. Corneal ectatic disorders are comprised of a class of diseases characterized by an ectatic, or misshaped, cornea. Corneal ectasia is typically caused by a weakening of the cornea, which can be due to a number of factors, including genetic causes, adverse side effects from ophthalmic refractive procedures such as LASIK, or excessive eye rubbing. We are currently targeting corneal disorders with our bio- activated pharmaceuticals including keratoconus, a rare disease, and corneal ectasia following refractive surgery. Keratoconus is mostly a hereditary, degenerative ectatic disease that is often first seen in older children or young adults in which the typically round, dome- shaped cornea progressively thins and weakens, causing a cone- like corneal bulge due to normal internal pressure of the eye. Corneal ectasia following refractive surgery is a serious complication that involves the cornea becoming weakened following a refractive procedure, such as LASIK, with symptoms similar to naturally occurring keratoconus. Refractive vision errors, or the inability of the cornea to properly focus light, are prevalent in the U.S. and abroad and include disorders such as presbyopia and myopia. Presbyopia is a natural part of aging due to the hardening of the eye' s crystalline lens over time, resulting in a loss of lens elasticity or the ability of the lens to change shape in order to focus incoming light on the retina. Myopia, or nearsightedness, is a vision condition in which close objects are seen clearly, but objects farther away appear blurred, and is usually caused by an elongation of the eyeball or a cornea having too much curvature. Presbyopia affects nearly everyone over the age of 40 while myopia first occurs in school- age children and typically progresses until about age 20.

Our pharmaceutical iLink platform uses a suite of novel single- use drug formulations that are bio- activated by our proprietary systems to address these corneal diseases. The iLink therapies, bioactivated upon the delivery of ultraviolet A (UVA) light to the cornea, induce a biochemical reaction called corneal collagen cross- linking (CXL). CXL strengthens, stabilizes and reshapes the cornea to treat corneal ectatic disorders. Our KXL System, which delivers UVA light to a large portion of the cornea, in conjunction with our Photrexa therapy, is approved by the FDA for use in the U.S. following removal of the epithelium (often referred to as " iLink epi- off "), a procedure familiar to ophthalmologists. In February 2021, we announced topline data for the Phase 3 trial for the iLink system using Epioxa therapy for the treatment of keratoconus without Our , myopia or other corneal diseases. Internationally, our iLink pharmaceutical therapies can also be administered with the KXL System to address corneal weakening caused by refractive surgery such as LASIK.

iLution Transdermal Pharmaceuticals

We are developing our iLution platform of cream- based drug formulations that are applied to the outer surface of the eyelid for dropless transdermal delivery of pharmaceutically active compounds for the treatment of certain anterior segment eye disorders. Several iLution platform products leverage an exclusive global licensing arrangement with Intratus Inc. to research, develop, manufacture and commercialize a patented, non- invasive, transdermal drug delivery formulation designed for application on the eyelid in the treatment of dry eye disease , presbyopia, glaucoma, and other ocular surface diseases and disorders. In January 2022, we commenced patient enrollment in Phase 2 clinical trials of two investigational drug candidates for the treatment of signs and symptoms of dry eye disease .

glaucoma of- effect than current standards of care products.

Research & Development

We devote significant resources to our R & D efforts, which are focused on developing new products, and enhancing the effectiveness, ease of use, safety, and reliability of our commercialized products. Our R & D objectives are:

- to advance glaucoma patient care through continuous improvement of our iDose and iStent platform technologies;
- to further enhance treatment options for keratoconus, while expanding iLink and CXL indications to include treatment for certain refractive and other rare- corneal conditions;
- to develop dropless, transdermal pharmaceutical therapies for glaucoma and corneal disorders; and
- to leverage our expertise in sustained release pharmaceutical retinal platforms to identify and develop viable treatment options for retinal diseases such as AMD, DME and RVO.A

considerable portion of our R & D investment **includes** pipeline includes the following programs: • iStent infinite PMA pivotal Phase 3 clinical trial for treatment of mild- to- moderate glaucoma; • **iLution Travoprost Phase 2a clinical trial** **iStent infinite MDR submission in the EU for advanced- refractory glaucoma** ; • **The U. S. IDE for the PRESERFLO MicroShunt**; • **second-Second** - generation extended release iDose TREX (pre-Phase 2b / 3 clinical) **program** ; and • **Future-Next** generations of the iDose platform (pre- clinical) ; • **NDA submission** . In addition to our organic R & D efforts noted above, we have licensed from Santen the PreserFlo MicroShunt. The MicroShunt is an ab- externo device being developed for treatment of **Epioxa** glaucoma where IOP is uncontrolled with maximum tolerated medical therapy or where progression of the disease warrants surgery. Santen submitted a Pre- Market approval (**Epi PMA**) application to the FDA in..... often referred to as “ **iLink epi** - on ²²) . As a result of this ; • **iLink third- generation Phase 2 clinical program**; • **3** - trial, we began to prepare for a new drug application (NDA) submission. However, in 2022- **2025** , based on feedback from the FDA during our pre- NDA submission meeting, we made the decision to commence- **commencement of a second confirmatory Phase 3-2** clinical trial for **iLink epi** **iLution Blepharitis**; • **iLution Travoprost (GLK - 311) Phase 2a clinical** on to support a future NDA submission. We commenced patient enrollment for this trial ; • **in the first quarter of 2023 and completed patient enrollment for this trial in the second quarter of 2023**. We are also advancing clinical trials for a third generation iLink therapeutic system. Internationally, our pharmaceutical therapies can also be administered with the KXL System to address corneal weakening caused by refractive surgery such as LASIK. We are investigating whether our bio- activated pharmaceutical products may also offer a means of improving the vision of patients with presbyopia, myopia or other corneal diseases. We have also developed our **iLution Dry Eye** platform of cream- based drug formulations..... signs and symptoms of dry eye disease (GLK- 301) and **Phase 2a clinical trial**; • **iLution presbyopia Presbyopia** (GLK- 302) . In January 2023, we announced promising initial Phase 2a **clinical results** for GLK- 301. Additionally, in late 2023 we commenced a Phase 2a trial ; • **IVT for iLution Travoprost for use in glaucoma..... capabilities, including Triamcinolone Acetonide SR, Multi- Kinase Inhibitor (GLK SR and Anti- 401) Phase 2 VEGF SR**. In December 2023, we commenced a first- in- human clinical trial for our retinal intravitreal multi- **AME, DME and RVO**; and • **IVT NCE Conjugate (GLK - 411) for** kinase inhibitor designed to treat wet AMD patients. If commercialized, these platforms would be designed to treat AMD, DME (pre- RVO, and other retinal diseases. The focus of our retinal research and development efforts is to develop potential treatment options with a longer duration- **of effect than current standards of..... of our R & D investment includes** clinical) trials and the collection of evidence that provide data for use in regulatory submissions and required post- market approval studies involving applications of our products. We expect our R & D and clinical expenditures to increase as we continue to devote significant resources to clinical trials and regulatory approvals of our pipeline products. We currently conduct R & D activities primarily in the U. S. but continue to expand our clinical capabilities to sites **internationally**. Sales and Marketing Our global sales efforts and promotional activities are currently aimed at ophthalmic surgeons and other eye care professionals. Our primary customers include ambulatory surgery centers (**ASC**), hospitals and physician private practices. In the U. S., we sell the majority of our products through a direct sales organization. Internationally, we sell our products primarily through direct sales subsidiaries **and but also** through independent distribution partners in certain countries in which we do not have a direct commercial presence or only maintain a modest commercial presence. In **2023-2024**, sales to **U. S. and international** customers **inside U. S. and internationally** accounted for 70 % and 30 % of our net sales, respectively. No single customer or distributor accounted for more than 10 % of our total net sales in **2023-2024** . For the year ended December 31, **2023-2024**, our iStent family of products, **iDose TR**, and related **glaucoma** accessories , accounted for approximately **75-79** % of our net sales, while our iLink therapies accounted for approximately **25-21** % of our net sales. Competition The medical technology and pharmaceutical industries are highly competitive. We compete with many companies, including divisions of companies much larger than us that may have greater resources and name recognition, and smaller companies that compete against specific products or in certain geographies. Furthermore, new product development, discoveries, and technological changes characterize the areas in which we compete. Our present or future products could be rendered obsolete as a result of development advances made by one or more of our present or future competitors or by other surgical or pharmaceutical therapy innovations. We must continue to develop and commercialize new products, technologies and therapies to remain competitive in the ophthalmology industry. We believe that we compete primarily on the basis of clinical superiority supported by extensive data and innovative features that enhance patient benefit, product performance, and safety. **The-7The** ophthalmic segment of the medical technology and pharmaceutical industries is dynamic and subject to significant change due to cost- of- care considerations, reimbursement levels, regulatory reform, industry and customer consolidation and evolving patient needs. The ability to provide products, technologies and therapies that demonstrate value, are reimbursed through government or third- party payors, improve clinical outcomes, demonstrate favorable safety profiles, and provide ease of use and reliability is becoming increasingly important for companies within ophthalmology. In glaucoma, our MIGS offerings primarily compete against Alcon, which acquired Ivantis Inc. **in January 2022**, Sight Sciences and New World Medical. Our procedural pharmaceutical product competes with AbbVie Inc. However, there are a considerable number of large and small companies providing other surgical glaucoma technologies, **7laser- laser** - based therapies, and pharmaceuticals that currently provide competition or with whom we may compete should our broad clinical development pipeline be approved and commercialized. In corneal disorders, we currently have the only FDA approved bio- activated pharmaceutical therapy for the treatment of keratoconus; however, there are certain pharmacies that compound pharmaceuticals that may be used by certain physicians in place of our Photrexa product, and globally we compete against numerous providers of corneal crosslinking therapies such as PeschkeTrade GmbH. Our **corneal disorder anterior segment** pipeline, if approved, would vastly expand our competition to numerous large companies such as AbbVie Inc., Alcon , **Inc.** and Johnson & Johnson, as well as some small companies that provide medical technology and pharmaceutical therapies for several areas including dry eye and refractive conditions. Our **retinal health posterior segment** pipeline, if approved, may face substantial competition from large pharmaceutical companies such as AbbVie Inc., Novartis AG, Genentech / Roche, Regeneron **Pharmaceuticals, Inc.** and Bayer **AG**, and there are also a

considerable number of large and small companies with development efforts in the field. Facilities, Manufacturing and Distribution **Our corporate headquarters, including certain administrative, laboratory, R & D and warehouse space, are located at a campus consisting of three office buildings comprising approximately 160,000 rentable square feet of space located in Aliso Viejo, California (Aliso Facility).** Our manufacturing operations for the iStent family of products and iDose TR are located in an approximately 120,000 square foot campus in San Clemente, California which is comprised of two main buildings, two suites and a warehouse. Our pharmaceutical therapies for keratoconus are primarily manufactured and supplied by third parties in the U. S. and Germany, and the manufacturing operations for the systems that bio- activate these therapies are located in approximately 60,000 square feet of space located in Burlington, Massachusetts. **In 2022, We recently reached agreement with the city of Huntsville,** we relocated our corporate headquarters **Alabama to build a brand- new 200,000 square foot** including certain administrative, laboratory, R & D and warehouse space, to three office buildings comprising approximately 160,000 rentable square feet of space located in Aliso Viejo, California (Aliso Facility). We currently intend to maintain manufacturing facilities **facility with construction anticipated to begin in 2026** for the iStent family of products and iDose TR at our San Clemente location for the foreseeable future. Our international subsidiaries also lease facilities in Australia, Brazil, Canada, Germany, Japan and the United Kingdom. In the **United States-U. S.**, we distribute our iStent family of products directly from our campus in San Clemente, California, or from a third- party distribution center located in Memphis, Tennessee. Our iDose TR and Photrexa products are distributed using third- party logistics providers. Our KXL Systems are distributed from our facility in Burlington, Massachusetts. Internationally, we distribute our products using third- party logistics providers in the Netherlands, Germany, **the United Kingdom,** Japan, Australia, Canada and Brazil. Intellectual PropertyThe strength of our competitive position depends substantially upon our ability to obtain and enforce intellectual property rights protecting our technology both domestically and internationally. We rely on a combination of intellectual property rights, including patents, trademarks, service marks, copyrights, trade secrets and other similar intellectual property, as well as customary contractual protections and security measures used to protect our proprietary, trade secret information. In the aggregate, our intellectual property assets are of material importance to our business. We are significantly dependent on our patent and other intellectual property rights and the failure to protect such rights could negatively impact our ability to sell current or future products or prohibit us from enforcing our patents or other intellectual **property-8property** rights against others. For additional information see the section titled Risks Related to Our Intellectual Property within Item 1A. **“Risk Factors”** of this Annual Report on Form 10- K. As of December 31, **2023-2024**, we owned or exclusively licensed in certain fields of use over **400-500** issued patents, pending U. S. patent applications, issued foreign patents and pending foreign patent applications. We have obtained licenses from various parties, including Intratus, Inc., Atillaps **Holdings, Inc.**, Iveena Delivery Systems, Inc. and Stuart Therapeutics, Inc. for patents, patent applications or other technology that we are currently or may in the future use in our R & D efforts. We may, from time to time, choose to acquire or license additional patents and patent applications, or we may choose to abandon, sell, or license certain Company patents and patent applications, depending on our needs. The issued patents that protect our commercial products and current product pipeline expire between **2024-2025** and **2042-2043**. **8Government- Government** Regulation **Our U. S. Regulation & ReimbursementOur** products and operations are subject to extensive and rigorous regulation by federal, state, and local authorities, as well as foreign regulatory authorities. These governmental agencies regulate, among other things, the research, development, testing, manufacturing, approval, labeling, storage, recordkeeping, advertising, promotion and marketing, distribution, post approval monitoring and reporting, and import and export of medical devices and drugs (including drug / device combination products) in their respective jurisdictions to assure the safety and effectiveness of medical products and pharmaceuticals for their intended use. In general, there has been a trend of increased regulation of medical device and drug products **ReimbursementThe** --- **Reimbursement The** FDA has broad regulatory authority over medical devices and drugs in the U. S. The FDA regulates, among other things, product safety, efficacy, manufacturing, advertising, labeling and safety reporting. Medical Device RequirementsEach medical device commercially distributed in the United States requires one of the following: (i) exemption from or clearance under a 510 (k) premarket notification; (ii) approval under a PMA application; or (iii) approval of a de- novo classification petition. The FDA classifies medical devices into one of three classes — Class I, Class II or Class III — depending on the degree of risk associated with each medical device and the extent of manufacturing and regulatory control needed to ensure its safety and effectiveness. Class III devices, which include our iStent family of products that produce the majority of our revenue, are deemed to pose the greatest risk, such as life- sustaining, life- supporting or implantable devices and devices deemed not substantially equivalent to a predicate device that the FDA has already cleared for marketing. Class III devices require FDA approval of the more demanding PMA application before marketing of the device can proceed. While the iStent, iStent inject W and the **PreserFlo-PRESERFLO** MicroShunt are categorized as Class III devices and thus have been or would be generally subject to the more rigorous PMA approval pathway, the FDA determined that an appropriate predicate device existed for the iStent infinite and that 510 (k) premarket notification was sufficient for clearance. PMA Approval PathwayIn a PMA application process, the manufacturer must demonstrate that the device is safe and effective for its intended use, and the PMA must be supported by extensive data, including data from preclinical studies and human clinical trials. If the FDA accepts the application for review, it has 180 days under the Federal Food, Drug, and Cosmetic Act (FDCA) to complete its review of a PMA, although in practice, the FDA’ s review can take up to several years. The FDA will generally conduct a pre- approval inspection of the applicant’ s or its third- party manufacturers’ or suppliers’ manufacturing facility or facilities to ensure compliance with the FDA’ s Quality System Regulation (QSR). Even after a PMA approval, the FDA may require post- approval conditions to ensure the safety and effectiveness of the device, including additional clinical studies or post- market surveillance. Failure to comply with the conditions of approval can **result-9result** in material adverse enforcement action, including withdrawal of the PMA approval. Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or

changes in the design performance specifications, which may affect the safety or effectiveness of the device, require submission of a PMA supplement. Clinical Trials of Medical Devices Clinical trials are almost always required to support a PMA for a Class III device. All clinical investigations must be conducted in accordance with the FDA's investigational device exemption (IDE) regulations. If the device presents a "significant risk" to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, showing with appropriate data that it is safe to test the device in humans and that the testing protocol is scientifically sound. ~~Regardless~~ **Regardless** of the degree of risk presented by the medical device, clinical studies must be approved by, and conducted under the oversight of, an Institutional Review Board (IRB) for each clinical site. During a study, the sponsor and any clinical investigators are required to comply with the applicable FDA requirements. After a trial begins, the sponsor, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Post-Market Regulation After a device is approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include: • ~~Establishment~~ **establishment** registration and device listing with the FDA; • QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process; • ~~Labeling~~ **labelling**, advertising and promotion regulations, which require that promotion is truthful, not misleading, fairly balanced and provide adequate directions for use and that all claims are substantiated, and also prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling; • FDA approval of product modifications of approved devices that affect safety or effectiveness or that would constitute a major change in intended use of an approved device; • ~~Medical~~ **medical** device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur; • ~~Correction~~ **correction**, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health; and • ~~Post~~ **post**-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device. ~~The FDA has broad regulatory compliance and enforcement powers.~~ If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in ~~any of, among the other things following sanctions:~~ • warning letters, ~~untitled letters,~~ fines, injunctions, consent decrees ~~and,~~ civil penalties ~~and criminal prosecution~~; • recalls, withdrawals, or administrative detention or seizure of products; ~~10~~ • operating restrictions or partial ~~or total~~ suspension ~~or total~~ ~~shutdown~~ of production; • refusing or delaying requests for approvals of new products or modified products; • withdrawing 510(k) clearances or PMA approvals that have already been granted; • refusal to permit the export or import of our products; ~~or~~ • ~~criminal prosecution~~. Drug Requirements The development and commercialization of drug products is subject to extensive regulation by governmental authorities in the U. S. Before marketing in the U. S., a drug must undergo rigorous preclinical and clinical studies and an ~~10~~ ~~extensive~~ **extensive** regulatory approval process implemented by the FDA under the FDCA. Several of our products, including our recently-approved iDose TR implants and our pipeline iLution cream-based formulations, are drug products that are subject to this regulatory approval process. Before commencing clinical studies in humans in the US, we must submit to the FDA an investigational new drug (IND) application that includes, among other things, the general investigational plan and protocols for specific human studies and the results of preclinical studies. Once clinical studies have begun under the IND, they are usually conducted in three phases and under FDA oversight. These phases generally include the following: Phase 1. Introduction into patients or healthy human volunteers to test for safety, dose tolerance and pharmacokinetics. Phase 2. Introduction into a limited patient population to assess the efficacy of the drug in specific, targeted indications, assess dosage tolerance and optimal dosage, and identify possible adverse effects and safety risks. Phase 3. Expansion to further demonstrate clinical efficacy, optimal dosage and safety within an expanded patient population. The results of drug development, preclinical studies and clinical studies must be submitted to the FDA as part of an NDA. The NDA also must contain extensive manufacturing information. The Prescription Drug User Fee Act (PDUFA) establishes timeframes for FDA review of NDAs and the 2007 Food and Drug Administration Amendments Act gave the FDA authority to require implementation of a formal Risk Evaluation and Management Strategy to ensure that the benefits of a drug outweigh its risks. At the end of the review period, the FDA communicates either approval of the NDA or a complete response listing the application's deficiencies. As part of the NDA approval, the FDA may require post-marketing studies, sometimes referred to as Phase 4 studies, to monitor the safety and effectiveness of approved drugs, which may limit further marketing of the drug based on the results of these post-marketing studies. If regulatory approval for a drug is obtained, the marketing of the drug will be limited to those diseases and conditions approved by the FDA and for which the drug was shown to be effective, as demonstrated through clinical studies and specified in the drug's labeling. Even if this regulatory approval is obtained, a marketed drug, its manufacturer and its manufacturing facilities are subject to continual review and periodic inspections by the FDA. The FDA ensures the quality of approved drugs by carefully monitoring manufacturers' compliance with its current Good Manufacturing Practice (cGMP) regulations, which contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packaging of a drug. The FDA may withdraw drug approval if compliance with post-marketing regulatory standards is not maintained or if safety or quality issues are identified after the drug reaches the marketplace. The FDA has determined that products previously regulated as drugs, which are comprised of a drug constituent part and a device part, may become subject to regulation as drug-led drug-device combination products. A drug-led drug-device combination product classification, such as iDose TR received, is based on the determination of the primary mode of action of the combination product. As a result, this change impacted the NDA submission for iDose TR, and may affect some of our pipeline products, such as future iDose platform drug-eluting implants. These products that are ~~considered~~ **11 considered** to be drug-led

drug- device combination products will require review and coordination by both the FDA's drug and device centers prior to approval, which may delay approval. In the U. S., a combination product with a drug primary mode of action generally would be reviewed and approved pursuant to the drug approval processes under the FDCA. In reviewing the approval application for such a product, however, FDA reviewers in the drug center will consult with their counterparts in the device center to ensure that the device component of the combination product meet applicable requirements regarding safety, effectiveness, durability and performance. Under FDA regulations, combination products are subject to cGMP requirements applicable to both drugs and devices, including the Quality System (QS) regulations applicable to medical devices. We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In ~~Heach~~ **each** of these areas the FDA and other regulatory authorities have broad regulatory compliance and enforcement powers, including the power to withdraw approvals. Health Care Regulatory Laws Additional laws and regulations also govern our business operations and products in the U. S., including among others:

- the federal health care Anti- Kickback Statute which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order, arrangement for, or recommendation of, items or services for which payment may be made, in whole or in part, under federal health care programs, **which impact our interactions with healthcare professionals**;
- the federal civil False Claims Act **which** prohibits, among other things, knowingly presenting or causing the presentation of a false or fraudulent claim for payment of government funds, or knowingly making, using, or causing to be made, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government. False Claims Act liability is significant in the healthcare industry because the statute provides for treble damages and significant mandatory penalties per false claim or statement for violations (adjusted annually for inflation);
- federal and state laws and regulations that govern the collection, dissemination, security, use, disclosure, deletion and confidentiality of patient- identifiable health and other proprietary and personally- identifiable information, in particular, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, as well as proposed or enacted state- level laws and regulations that create data privacy and security rights for state residents and obligations for certain entities, such as the California Consumer Privacy Act, the California Privacy Rights Act ~~that went into effect January 1, 2023~~, the Virginia Consumer Data Protection Act and the Colorado Privacy Act, **among other states**.

HIPAA created federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program;

- the Physician Payments Sunshine Act, which requires applicable manufacturers like us to report annually to the CMS information related to payments and other " transfers of value " made to certain healthcare providers, including physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse- midwives, and teaching hospitals, and ownership and investment interests held by such healthcare providers and their immediate family members; and
- federal and state government price reporting laws that require us to calculate and report certain drug pricing metrics to government programs, such as the average sales price of our Photrexa and iDose TR products, where such reported prices may be used in the calculation of reimbursement and / or discounts on our marketed pharmaceutical products, and prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs, including federal laws that require any company ~~that~~ **12that** participates in the Medicaid Drug Rebate Program (MDRP) also to participate in the Public Health Service's 340B drug pricing program (340B program) in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B " ceiling price " for the manufacturer's covered drugs. Certain states also mandate implementation of corporate compliance programs, require adherence to the medical device or pharmaceutical industry's voluntary compliance guidelines, impose restrictions on manufacturer marketing practices, require registration or licensing of manufacturers and their sales representatives, and / or require tracking and reporting of gifts, compensation, and other remuneration to healthcare professionals and entities.

~~12Violations~~ **Violations** of the health care regulatory laws described above; may subject us to administrative, civil, and criminal penalties, including imprisonment of individuals, the imposition of significant fines, monetary penalties, and damages, exclusion from participation in (or reimbursement for our products from) federal health care programs like Medicare or Medicaid, imposition of compliance obligations or monitoring, curtailment or restructuring of our operations, and damage to our reputation. Medical Device Reimbursement- Medicare Ambulatory surgery centers, hospitals and physician private practices that purchase our medical device products typically bill various third- party payors, such as government programs, private insurance plans and managed care programs, to cover all or a portion of the costs and fees associated with the therapeutics or procedures in which our products are used and bill patients for any applicable deductibles or co- payments. In the U. S., there are distinct billing codes that are used by healthcare providers to report the provision of medical procedures and the use of supplies for specific patients to payors. There are different categories of Current Procedural Terminology (CPT ®) codes (Category I, II and III) based on the procedure or supply. In the U. S., physicians are typically paid separately from the facility for surgical procedures involving our products. Physician fee payment rates for products covered by temporary CPT codes are set by the multi- state, regional contractors, or **Medicare Administrative Contractors (MACs)**, of which there are currently seven, that are responsible for administering Medicare claims. MACs have in the past, and may in the future, change coverage terms, and there can be no assurance that coverage and adequate reimbursement will be obtained from, or maintained by, the MACs. **In April** ~~Effective beginning in 2022, the temporary Category III CPT codes associated with payment rates for procedures related to our iStent and iStent inject W products, used in conjunction with cataract surgery, converted to permanent Category I codes for facility fee and physician fee payments furnished in both the hospital outpatient and ambulatory surgery center settings. As compared to the payments rates in effect in 2021 under the Category III CPT code, the CMS 2022 Medicare payment rates reflected a significantly lower physician fee~~

involving procedures of the implantation of trabecular bypass stents, such as our iStent family of products, in conjunction with cataract surgery, while the facility fee schedule related to reimbursement for surgeries that include implantation of trabecular bypass stents, such as our iStent family of products, in conjunction with cataract surgery, reflected a slight decrease in payment rate to an ambulatory surgery center, and an increase in reimbursements to a hospital. The CMS Medicare payment rates in effect for 2023 were not materially modified from the 2022 rates. Even though a permanent billing code has been assigned to a product, there is no guarantee that coverage will be provided or that that current level of reimbursement will remain the same. Additionally, effective in 2022, we obtained a temporary Category III CPT code associated with payment rates for facility fee payments for standalone insertion of an aqueous drainage device in the ambulatory surgery center and hospital setting, which is the procedure that such facilities would use with our iStent infinite product, that were lower than anticipated. On November 1, 2023, CMS published its final rules on 2024 Medicare physician fee and facility fee payment rates (2024 Final Rule), which took effect on January 1, 2024. The 2024 Final Rule does not materially modify the 2023 rules with respect to physician fee payment rates for procedures using our iStent family of products in conjunction with cataract surgery, but does contain increased facility fee rates for such procedures, in both the ASC and hospital settings. In addition, the 2024 Final Rule contained significant increases in the facility fee rates for ASCs and hospitals that perform iStent infinite procedures in a standalone setting under its temporary Category III CPT code. In June 2023, five of the seven MACs **released draft** published proposed local coverage determinations (LCDs) that included **would confirm** reimbursement coverage of **the standalone procedure utilizing the** iStent infinite, which received FDA clearance in August 2022, **and** . The proposed LCDs released by the five MACs also contained additional rules that would result in certain ophthalmic goniotomy and canaloplasty procedures being categorized as investigational and therefore not covered or reimbursed by Medicare. In October and November 2023, the five MACs released final LCDs, confirming **confirm** reimbursement coverage of the standalone procedure utilizing the iStent infinite and non-coverage for certain procedures, including the ophthalmic canaloplasty procedure utilizing our iPRIME product. Further, the final LCDs indicated that surgical MIGS procedures should not be performed in combination with other **surgical** MIGS or surgical glaucoma procedures **(but did** . In December 2023, prior to their respective effective dates, the five MACs rescinded the final LCDs and determined there would be no **not prohibit** change in the current status of coverage for **use of a procedural pharmaceutical such as our iDose TR, in combination with surgical MIGS procedures**). **These draft LCDs were finalized in October 2024 and took effect on November 17, 2024** . The other two MACs have taken preliminary steps to assess coverage of iStent infinite through **temporary** local coverage article (LCA) updates. In the case of **each of these seven two** MACs, coverage of the iStent infinite is **currently** determined on a case-by-case basis. **On January 1** Prior to expiration of a temporary CPT code, there are two options: submit **2025, CMS' final rules on 2025 Medicare physician fee and facility fee payment rates (2025 Final Rule)** **became effective. The 2025 Final Rule did not materially modify the 2024 Medicare physician fee and facility fee payment rates** application for a five-year extension of the temporary code. In connection with **respect** a transition to a permanent code **physician fee and facility fee payment rates** for procedures using our iStent **family of** infinite product in a standalone setting, both the physician fee and facility fee will be reevaluated. In some cases, the physician fees and / or facility fees have been decreased at the time codes are transitioned from temporary to permanent. There is no published Medicare payment schedule at the national level for physician payment amounts for temporary Category III CPT code products . The physician payment rate is left to the discretion of the regional Medicare Administrative Contractors (MACs), with each MAC separately determining coverage and no assurance that coverage and adequate reimbursement will be obtained from, or maintained by, the MACs. MACs have in the past, and may in the future, change coverage terms . We estimate that approximately 80 % of procedures utilizing our **iStent family of products** trabecular micro-bypass technologies in the U. S. are performed in the ambulatory surgery center setting and the remaining estimated 20 % of procedures are performed in the hospital. Drug Reimbursement - Medicare **On April 2, 2024, CMS assigned a unique, permanent HCPCS J - Medicare Our code for iDose TR indicated for the reduction of intraocular pressure in patients with open- angle glaucoma or ocular hypertension. The new J- code for iDose TR, J7355, became effective July 1, 2024. J- codes are used by U. S. government and commercial payers, as well as surgeons, 13 to streamline the billing and reimbursement process for procedural pharmaceuticals administered by a healthcare professional, such as iDose TR, along with other certain treatments. In addition to the J- code, on March 21, 2024, CMS assigned the CPT codes that are designed to be used to cover the procedural component of iDose TR, 0660T and 0661T, to ambulatory payment classification 5492 (Level 2 Intraocular Procedures), effective April 1, 2024. The professional fees associated with an iDose TR procedure are being set by each individual MAC separately. Our** Photrexa pharmaceutical therapy has received a permanent Healthcare Common Procedure Coding System (HCPCS) J- code **J2787** that covers the cost of the drug. We have also obtained temporary Category III CPT code for the professional fees associated with CXL procedures done in a physician office setting. **We have applied for a HCPCS J- code for our iDose TR procedural pharmaceutical product. We have already obtained a temporary Category III CPT code for the facility and professional fees associated with the implantation procedure of an iDose TR in an ASC setting. As a condition of having our iDose TR product covered under certain federal healthcare programs such as Medicare and Medicaid, we are required to participate in the MDRP with respect to all of our pharmaceutical products. Participation in the MDRP requires us to calculate and report certain pricing metrics to the government, comply with certain pricing limitations **any and** pay a rebate to each state Medicaid program for our covered products based on utilization of our products by Medicaid beneficiaries. Any company that participates in the MDRP **must** also **must** participate in the 340B drug pricing program (the "340B program"). The 340B program, which is administered by the Health Resources and Services Administration, requires participating companies to agree to charge statutorily defined covered entities no more than the 340B " ceiling price " for covered outpatient drugs. The 340B **program** ceiling price is calculated using a statutory formula, which is based on pricing data calculated under the MDRP. To the extent applicable, these and other similar legislation or regulations will reduce the prices we can charge, and impact the**

rebate amount we must pay on sales of our products subject to those laws or regulations, particularly on sales to our customers if they qualify as covered entities eligible to receive the discounted 340B program ceiling price. Any changes to the limitations, calculations, or scope of these programs could negatively impact the results of our operations. **Our** We cannot predict how our participation in the MDRP will affect affects our profitability through (including the potential for need to increase increase in our overall Medicaid rebate liability and the obligation to charge reduced prices to covered entities). Reimbursement – Commercial Insurance Plans In the U. S., no uniform policy of coverage and reimbursement exists among third- party commercial payors; coverage and reimbursement can differ significantly from payor to payor. In addition, payors continually review new products for possible coverage and existing products for changes in coverage and can, without notice, deny coverage. **14International-- International Regulation & Reimbursement Regulation In Reimbursement Regulation In** addition to regulations in the U. S., we are subject to a variety of regulations in other jurisdictions governing clinical trials, commercial sales and distribution of our products and reporting of payments to physicians. Whether or not we obtain FDA approval for a product, we must obtain authorization before commencing clinical trials or obtain marketing authorization or approval of a product under the comparable regulatory authorities of countries internationally. The approval process varies from country to country and the time may be longer or shorter than that required for approval in the U. S. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. In addition, certain countries have adopted transparency legislation that requires us to report contracts with or payments made to physicians in those countries and many have enacted anti- kickback laws and regulations, which generally prohibit the offer, receipt, or payment of remuneration in exchange for or to induce the use of our products. Similar to the trend within the U. S., certain major international markets are also moving toward more stringent regulatory frameworks for medical device and drug products. For example, in May 2017, the EU adopted a new regulatory scheme for medical devices under the Medical Device Regulation (MDR). The MDR became effective in May 2021 and the European Commission approved an extension of the transition period through 2028 for qualifying products. The MDR will bring brings significant new requirements for many medical devices, including enhanced requirements for clinical evidence and documentation, increased focus on device identification and traceability, new definitions and registration of economic operators throughout the distribution chain, and additional post-market surveillance and vigilance, which could result in substantial additional expense. Additionally, the bio- activated therapy used with our crosslinking **14crosslinking** device to treat keratoconus in international markets, which is currently classified as a medical device in the EU and certain other countries, could be reclassified as a drug product, which would impose an entirely new regulatory framework on us and our contract manufacturers for this product, and compliance may prove costly and difficult or may not be achievable at all. The EU has also adopted increasingly stringent data protection and privacy rules that have and will continue to have a substantial impact on the use of patient data across the healthcare industry. The EU General Data Protection Regulation (GDPR) became effective in May 2018 and applies across the EU. The United Kingdom has adopted the UK Data Protection Act 2018, a substantially equivalent version of the GDPR. The GDPR is wide- ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third- party processors. **Failure See the section titled Risks Related to comply Our Business with within Item 1A. “ Risk Factors ” of this Annual Report on Form 10- K for more information related to** the GDPR requirements may result in costly government enforcement actions, private litigation, and negative publicity, each of which could further result in reputation damage and our business, financial condition, results of operations or prospects could suffer. Reimbursement Internationally, reimbursement levels vary significantly by country and by region within some countries. Reimbursement is obtained from a variety of sources, including government-sponsored and plans, private health insurance plans, and combinations of both. Some countries require additional clinical data, or may impose additional obligations, such as payment of rebates, before granting or expanding coverage and reimbursement for our products. In general, obtaining broad- based reimbursement and adequate payment for new technologies is more difficult in these markets than in the U. S. Many countries require new medical technologies to not only be safe and effective, but also to be able to demonstrate clinical benefits that outweigh the costs when compared to the standard of care. As in the U. S., reimbursement decisions can change, resulting in the elimination or reduction of reimbursement payments, which could adversely affect our financial results and our ability to invest in and grow our business. **15Other-- Other** Regulations Our operations and many of the products we manufacture or sell are subject to extensive regulation by numerous other governmental agencies, both within the U. S. and internationally. In the U. S., apart from the agencies discussed above, our facilities, operations, employees, products (their manufacture, sale, import and export) and services are regulated by the Environmental Protection Agency, the Occupational Health & Safety Administration, the Department of Labor, Customs and Border Protection, the Department of Commerce, the Department of Treasury, the Department of Justice and others. State agencies also regulate our facilities, operations, employees, products and services within their respective states. Government agencies internationally also regulate public health, product registration, manufacturing, environmental conditions, labor, exports, imports, bribery and corruption and other aspects of our global operations. These regulatory agencies and any current or future legislation could impact our business operations, reimbursement for our products, and the healthcare environment generally, which could adversely affect our ability to operate our business and our financial results. We cannot estimate the expenses we may incur to comply with potential new laws or changes to existing laws, or the other potential effects these laws may have on our business. **Additionally, the U. S. government has recently made statements and taken certain actions that have created significant uncertainty about the future relationship between the U. S. and various other countries with respect to trade policies, treaties, government regulations and tariffs, which may lead to the imposition of tariffs and export control restrictions affecting certain products manufactured in certain other countries. We believe our exposure to such**

potential tariffs and export restrictions is limited as we do not source a significant amount of our raw materials and product components from countries other than the U. S.; however, unfavorable government policies on international trade, such as export controls, or tariffs, may increase the cost of manufacturing our commercialized products or developing our pipeline products, affect the demand for our products (if and once approved), or restrict our access to raw materials and 15 components used in the manufacture of our current products and the development of our future products, each of which could negatively impact our financial condition and results of operations.

Human Capital Management Glaukos Management Glaukos is committed to developing a comprehensive, cohesive and positive employee experience. We consider talent attraction, development, engagement and retention a key driver of our business success. As of December 31, 2023-2024, we had 907-995 full- time employees. Our Board of Directors, through the Compensation, Nominating and Governance Committee, retains direct oversight of our human capital management process, including demographics **executive succession planning**, talent development, employee retention, material aspects of employee compensation as well as inclusive recruitment, retention and compensation efforts. **Additionally, the Compensation, Nominating and Governance Committee assists management with the implementation of the Company's diversity strategy.** We report on human capital matters at each regularly scheduled Board of Directors meeting and periodically throughout the year. The most significant human capital measures or objectives that we focus on in managing our business and our related human capital initiatives include the following:

- **Workforce Diversity:** We believe that truly innovative companies must find new ways to address the marketplace's needs and the most effective innovation happens when our workforce represents a diversity of ideas and experiences. We embrace diversity in our employee recruiting, hiring, and development practices. Our workforce was made up of 40 % female employees and 42 % racially or ethnically diverse employees as of December 31, 2023. During 2023, of the promotions that were earned within our workforce, 51 % were earned by female employees and 52 % were earned by racially or ethnically diverse employees.
- **Inclusion and Belonging:** We strive to create a work environment that emphasizes respect, fairness and dignity and do not tolerate discrimination or harassment. Individuals are evaluated based on merit, without discrimination, including discrimination based on race, color, religion, national origin, citizenship, marital status, gender (including pregnancy), gender identity, gender expression, sexual orientation, age, disability, veteran status, or other characteristics protected by law. We are committed to providing equal opportunities to every member of our workforce. To further celebrate the rich perspectives and experiences that arise from racial, ethnic, socio-economic, sexual, gender, physical and religious diversity, we formed the Diversity, Equity and Inclusion Forum, comprised of Glaukos employees from across the globe who serve as an advisory group to help promote our inclusive culture. We also evolved from our traditional work arrangements by implementing a hybrid office / home work model in 2022 that provides flexibility to our employees, increases opportunities to attract qualified and diverse talent, and enhances leaders' skills to focus on productivity and outcomes.
- **Health, Safety, and Wellness:** We are dedicated to the safety and well- being of our employees. We continue to provide our employees with exceptional medical and dental benefits. In the U. S. we provide vision benefits for our employees and their dependents at no cost to them. In 2024 and 2023, we offered a wellness credit to all U. S. employees that provides reimbursement for certain health- related expenses such as gym memberships -- **memberships**, to incent a healthy lifestyle, **as well as a mental health toolkit that was developed to promote the various resources, programs and tools available to help support our U. S. employees and their families.** We provide healthy snacks at all of our headquarters' locations, and at certain sites we have implemented " Wellness Wednesdays " to provide shoulder massage services to our employees to enhance their well- being. We also established a cross- departmental Safety Committee to communicate safety information to their respective teams, act as their department' s liaison to bring up safety concerns or questions, and work to improve safety within the organization. Glaukos conducts periodic risk assessments and institutes controls intended to eliminate hazards and minimize risks. **In 2024, we also implemented a voluntary disability insurance program for our California state employees.**
- **Philanthropy and Volunteerism:** We created the Glaukos Charitable Foundation to assist the company in its philanthropic endeavors. In 2023-2024, Glaukos donated approximately \$ 10-6. 5-6 million worth of its products to assist individuals in need. We regularly hold local volunteer events and fundraising campaigns, including approximately 21-30 in 2023-2024, to encourage our employees to give back to our communities, a commitment that we further support by offering employees paid time off for charitable volunteering. One of our more impactful volunteer events involved Glaukos employees adopting over 195-200 disadvantaged families globally to help provide a more special holiday experience. **We also have** In 2022, we implemented an automated charitable giving platform that allows employees to donate to the Glaukos Charitable Foundation, or any other 501 (c) (3) charitable organization, through payroll deductions.
- **Training and Development:** Employees receive regular development feedback through quarterly management check- ins during which they are encouraged to cultivate new skills and opportunities. We coach our leaders to facilitate effective conversations, and we measure the effectiveness of these conversations by surveying our employees. **All people leaders are invited to participate in two formal leadership development programs. And Glaukos offers a variety of open enrollment leadership classes.** In addition to training and development opportunities, all new employees are required to participate in ~~substantial~~ training seminars to introduce them to Glaukos' products, pipeline and position within ophthalmology. We value knowledge and continuous improvement and conduct informational and training sessions to further expose our employees to different departments, projects and business priorities. Our company- wide learning management system contains thousands of learning activities and expanded leadership and technical training -- and is available to employees worldwide.
- **Compensation and Benefits:** To attract, retain and recognize talent, we aim to ensure merit- based, equitable compensation practices and strive to provide competitive compensation and benefit packages to our workforce. Employees at all levels are eligible for discretionary cash bonuses. To align employees **with 16** with the organization' s performance, all U. S. employees are eligible to receive new hire and annual awards of restricted stock units. In furtherance of our commitment to internal pay equity and pay transparency, Glaukos conducts a global annual pay equity analysis to evaluate compensation distribution, which analysis is also conducted in connection with new hires and

promotions. **In** ~~Despite the difficulties presented by COVID-19, in~~ recent years we expanded our global benefits programs, including broadening our employee assistance program globally. In the U. S., we added elderly and childcare and fertility treatment assistance. In 2022, we enhanced our global leave policies for maternity, adoption, baby bonding and medical disabilities to supplement disability and statutory benefits in such a way that employees receive 100 % salary for up to 12 weeks. In the U. S., we also enhanced our medical benefit platform with wellness activities, incentives, and benefits including reimbursement for eligible wellness expenses, onsite biometric screening, onsite **voluntary** flu and COVID vaccine events, health surveys, apps and other resources to encourage and support our employees in achieving their best health. **In 2024, we also introduced a student loan repayment program available to all full-time U. S. employees, pursuant to which the Company will make a monthly payment directly to an employee's eligible student loan, up to a lifetime maximum.** •

Employee Retention: Employee retention is crucial for the success of our organization. By retaining our employees, we can experience savings on hiring and training costs, preserve institutional knowledge and strengthen our culture. In order to keep our turnover rates low, we focus on maintaining a positive work environment where employees want to stay, offer competitive compensation and benefits, encourage career development and recognize and reward employees for their achievements and accomplishments. In **2023-2024**, our overall employee voluntary turnover rate was **6.9 %**, an increase from our 2023 rate of 5.3 %, **but** a decrease from our 2022 rate of 11.0 % and our 2021 **• Workforce Inclusiveness: We strive to rate create of 13 a work environment that emphasizes respect, fairness and dignity and do not tolerate discrimination or harassment.** • **Glaukos is an equal opportunity employer, and we are focused on hiring and promoting the most qualified individual for each position. We incorporate fairness and inclusiveness through our employee recruiting, hiring, and development practices. Individuals are evaluated based on merit, without discrimination. We are committed to providing equal opportunities to every member of our workforce. We believe that truly innovative companies must find new ways to address the marketplace's needs, and the most effective innovation happens when our workforce represents a diversity of ideas and experiences. Our workforce was made up of 41 % female employees and 44 % racially or ethnically diverse employees as of December 31, 2024. During 2024, of the promotions that were earned within our workforce, 46 % were earned by female employees and 55 % were earned by racially or ethnically diverse employees. To provide flexibility and increase opportunities to attract qualified and diverse talent, we have evolved from our traditional work arrangements by implementing a hybrid office / home work model, for eligible positions.** • For additional information on human capital matters, please see our most recent Sustainability Report, which is available on our website at [www. glaukos. com](http://www.glaukos.com). The information found on, or otherwise accessible through, our website is not incorporated by reference into, nor does it form a part of, this report or any other document that we file with the Securities and Exchange Commission (SEC). **17Available -- Available** InformationOur Annual Report on Form 10- K, Quarterly Reports on Form 10- Q, Current Reports on Form 8- K and amendments to reports filed or furnished pursuant to Sections 13 (a) and 15 (d) of the Exchange Act, are available on our web site at www. glaukos. com, free of charge, as soon as reasonably practicable after the electronic filing of these reports with, or furnishing of these reports to, the SEC. In addition, the SEC maintains a web site at www. sec. gov that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including us. **18Item 17Item**

1A. Risk FactorsThe risks **and uncertainties** discussed below are not the only ones facing our business but do represent those risks that we believe are material to us. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also harm our business. Please read the cautionary notice regarding forward- looking statements **preceding Part I, Item 1 in this Annual Report** under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” **22Risks Related to Our Business**The commercial success of our ~~recently-approved~~ iDose TR is dependent upon multiple factors, the failure of any one of which could materially impact the prospects of this product and our business. Our iDose TR travoprost intracameral implant was approved for sale in the U. S. by the FDA in December 2023 **and we began commercializing the product in a controlled manner in February 2024.** Its **ultimate** commercial success will depend upon a number of factors, including physician **training on and** adoption of the use of this product, **establishment of consistent reimbursement**, our ability to manufacture product in volumes sufficient to meet customer demand, marketing in compliance with label restrictions, satisfactory patient outcomes, particularly **as we continue** at the outset of our commercial launch, product pricing, duration of efficacy, and the availability of commercial payor coverage and adequate reimbursement for the product. Our failure to successfully commercialize the iDose **TR** based upon these or other factors could materially adversely impact our net sales, our business or our financial condition. Unfavorable global and regional conditions have adversely affected, and could in the future materially and adversely affect, our business, results of operations, financial condition, liquidity, and cash flows. Recent geopolitical conflicts, natural disasters and **the public health crises, such as COVID- 19 pandemic,** have led to or exacerbated certain unfavorable global and regional macroeconomic conditions, including inflation, volatility in the financial and credit markets, higher interest rates and capital costs, labor shortages, increased energy costs, and currency fluctuations, which have had, and could continue to have, an adverse effect on the global economy, the regional economies that we serve and our business, results of operations, financial condition, liquidity and ability to access our existing cash, cash equivalents and investments. Continuation or worsening of these unfavorable global and regional conditions **or similar new events or crises,** could have a material adverse effect on our operations, including through foreign exchange rate headwinds, higher operating expenses and lower operating margins, and cause us to need to seek additional capital, which may not be available to us on favorable terms or at all. In recent years, unfavorable economic conditions have also adversely impacted several financial institutions, including some financial institutions with whom we have banking relationships, and some banks have recently failed and gone into receivership. If banks and other financial institutions with whom we have banking relationships enter receivership or become insolvent in the future, we may be unable to access, and we may lose, some or all of our existing cash and cash equivalents to the extent those funds are not insured or otherwise protected by the FDIC. Public health crises, such as the COVID- 19 pandemic, have adversely affected, and could in the future adversely affect, our

business, results of operations, financial condition, liquidity, and cash flows. We are subject to risks associated with public health crises, **including such as** those **related experienced due** to the COVID- 19 pandemic. **The COVID- 19 pandemic has had, and could continue to have, an adverse effect on our business, results of operations, financial condition, liquidity and cash flows. Other future public health crises may also have a negative impact on our business.** In particular, we have experienced, and may in the future experience, financial or operational impacts as a result of **such COVID- 19 or other** public health crises which may be material, including: • Impacts or delays to our product development efforts, including due to slowdown of new patient enrollment in clinical trials such as we experienced in our 2020 and 2021 iDose clinical trial, or regulatory clearances and approvals; • Costs associated with protecting the health of our employees and adhering to any guidance or orders of various governmental authorities, such as masking, testing, and social distancing requirements; • Risks associated with remote work, including increased cybersecurity risk; ~~19~~ • Widespread staffing shortages and turnover, including in ambulatory surgery centers, and mandatory and voluntary quarantining, which may impact elective procedures; **18** • Outbreaks of disease in our facilities, which could require us to temporarily shut down manufacturing operations or cause a disruption to, or shortage in, our workforce; • Delays in shipments of our products, which could harm our customer relations and adversely impact our competitive positioning and sales, including as a result of longer lead times, delays, higher prices and unfulfilled deliveries of our supply chain and development partners, each of which we continued to experience in **2023-2024** and **some of which we** anticipate will continue into the near future; • Restrictions on our personnel' s ability to access customers and clinical sites for training and support; and • Volatility in credit or financial markets. If the supply and / or manufacture of our principal revenue-producing products, the iStent family of products, ~~and~~ our Photrexa therapies, **or the iDose TR** is materially disrupted, it may adversely affect our ability to manufacture products and could reduce our gross margins and negatively impact our operating results. Our sole manufacturing location for our iStent and iDose products is an approximately ~~101-120~~, 000 square foot campus located in San Clemente, California, where we manufacture, inspect, package, release and ship nearly all of our implanted device products. We conduct substantially all of our research and development (R & D) activities, customer and technical support, and management and administrative functions at our corporate headquarters in Aliso Viejo, California (Aliso Facility). If either of our San Clemente or Aliso Facility suffers a crippling event or a natural disaster such as an earthquake, fire or flood, **or if we lose insurance coverage for or are unable to renew insurance on these facilities, as some California residents have experienced**, this could materially impact our ability to operate. Additionally, we rely on a limited number of third- party suppliers, in some cases sole suppliers, to supply components for the iStent, the iStent inject models, the iStent infinite, the iDose TR, and our other pipeline products. If any one or more of our suppliers cease to provide us with sufficient quantities of components or drugs in a timely manner or on terms acceptable to us, we would have to seek alternative sources of supply. Because of factors such as the proprietary nature of our products, our domestic and international quality control standards and regulatory requirements including the FDA' s Quality System Regulation, the European Union' s Medical Device Regulation, and Current Good Manufacturing Practices (**cGMP**) regulations, we may be unable to obtain components or quickly engage replacement suppliers, who may not have access to previous suppliers' proprietary processes, if our component suppliers are found to be in violation of such standards, which could delay or impact our business, including regulatory approval timelines. If our manufacturing facilities or those of any of our component suppliers or contract facilities are found to be in violation of applicable laws and regulations or fail to adequately remediate any issues discovered during an audit, the FDA or other regulatory bodies could take enforcement action. Despite our efforts to maintain an adequate supply of inventory, the loss of these suppliers, or their inability to provide us with an adequate supply of components or products, could cause delay in the manufacture of our products, thereby impairing our ability to meet the demand of our customers and causing significant harm to our business. Any disruption of this nature or increased expense could harm our commercialization efforts and adversely affect our operating results. Our corneal health Photrexa therapies **, and our Epioxa pharmaceutical therapies, which are not yet approved by the FDA,** are produced by a small number of contract manufacturing organizations. The systems that bio- activate our Photrexa **and Epioxa** therapies are primarily manufactured in Burlington, Massachusetts. Any material disruption to the manufacture of these corneal health products could also adversely affect our operating results and clinical efforts. We have incurred significant losses since inception and our operating results can be unpredictable and may fluctuate significantly from quarter to quarter, requiring substantial capital and operating expenditures for our business to operate and grow. These factors could adversely affect our business, financial condition, results of operations and the trading price of our common stock, and limit our ability to reach sustained profitability. Since the Company' s inception in 1998, we have incurred significant operating losses. Although we have been profitable for certain periods in our operating history, there can be no assurance that we will be profitable or generate cash from operations in the future. As of December 31, **2023-2024**, we had an accumulated deficit of approximately \$ ~~599-745~~. **14** million, principally comprised of costs incurred in our clinical **trial trials**, R & D programs, our selling, general and administrative expenses, and from amortization expense related to our **acquired** developed technology intangible assets included in cost of sales. We have funded our operations to date from the sale of equity securities, including our June 2015 initial ~~20public~~ **public** offering, the issuance of notes payable, cash exercises of stock options and warrants to purchase ~~equity~~ **equity** securities, cash generated from commercial operations and the issuance of the Company' s 2.75 % convertible notes due 2027 (Convertible Notes) **, which were fully exchanged, converted or redeemed in 2024**. Our operations to date have been, and our future growth and success will be, impacted by our ability to expand our business, including the success of our marketing and sales efforts, our timely satisfaction of regulatory requirements, and our overall ability to maintain a competitive position. To implement our global business strategies we have made, and expect to continue to make, significant investments in R & D activities, clinical studies, expanding our manufacturing capabilities, growing our sales and marketing organization, ~~engaged~~ **engaging** in market access activities, enforcing and defending our intellectual property rights, acquiring companies or in- license products and intellectual property, building our general and administrative infrastructure, and obtaining regulatory clearance or approval to commercialize our pipeline product globally and expand our

existing products into international markets or products. We expect our expenses will continue to increase as we pursue these objectives. While we believe we have sufficient cash to fund our operations for at least the next 12 months from the date our consolidated financial statements for the year ended December 31, ~~2023~~ **2024** are made publicly available, our ability to reach sustained profitability and generate positive cash flow in the future is highly uncertain. Additionally, our net sales may experience volatility due to a number of factors, many of which are beyond our control, including, among other things, fluctuating demand, pricing pressures applicable to our products, changes in foreign currency exchange rates, Medicare payment rates established by U. S. Centers for Medicare & Medicaid Services (CMS) or **Medicare Administrative Contractors (MACs)**, commercialization of our new ~~and existing~~ products ~~and~~, the marketing of competitive products, results of clinical research and trials, regulatory approval requirements and timings, legislative changes affecting our products, variances in the sales terms, an increase in demand for our patient assistance and / or free drug programs, supply chain and inventory management, shortage **or increased cost** of raw materials, seasonality in the timing or volume of customer orders ~~and~~, the length of our sales cycle, **and reductions in revenue associated with our participation in Medicaid Drug Rebate Program (MDRP)**, which varies and may be unpredictable. As a result, you should not rely solely on our results in any past period as an indication of future results and you should anticipate that fluctuations in our quarterly and annual operating results may continue and could generate volatility in the price of our common stock. We believe that quarterly comparisons of our financial results should not be relied upon as an indication of our future performance. Our success depends on our ability to continue to generate sales of our commercialized products and develop and commercialize additional products, which we may not be able to accomplish. Our primary sales- generating commercial products have been the iStent, the iStent inject and its successor, the iStent inject W, as well as our Photrexa therapies, which we acquired in connection with our acquisition of Avedro, Inc. (Avedro) in 2019. While we expect to continue to derive a significant portion of our net sales from the iStent, the iStent inject models, the iStent infinite and the Photrexa therapies, as well as our iDose TR product, which was ~~recently~~ approved by the FDA **in December 2023 and which we began commercializing in a controlled manner in February 2024**, it is important that we continue to build a more complete product offering. Developing additional products is expensive and time- consuming. Our research programs may fail to yield product candidates for clinical development despite showing initial promise. If we are unable to successfully commercialize additional products, our business prospects would be materially affected. Even if we are successful in developing our additional pipeline products, the success of our new product offerings is inherently uncertain and our products may not receive regulatory approval, may receive approval that requires restrictive labeling, or may not be profitable. Any current or new products could also quickly be rendered obsolete by changing customer preferences, third party payor reimbursement levels, or the introduction of competing products that (i) embody superior technologies, features, safety, quality or efficacy, (ii) reflect a broader label indication, or (iii) are available at lower prices. Our competitors include large publicly traded companies or divisions thereof and have more resources, greater name recognition, longer operating histories, more established relationships with healthcare professionals, customers and third- party payors, broader products lines, more established sales and marketing programs and distribution networks, and greater experience in obtaining regulatory clearance or approval. Additionally, the period of orphan drug exclusivity with respect to our Photrexa pharmaceutical therapy expired in ~~April~~ **2023**, which could allow competitive products to enter that market. ~~21As-20As~~ our growth strategy turns increasingly global, we are, and will continue to be, subject to a variety of risks associated with our international operations, which could adversely impact our results of operations and financial condition. Our existing foreign operations, as well as our planned international growth, expose us to additional uncertainty and risks beyond regulatory authorization and reimbursement levels. We sell our products through direct sales organizations and a network of third- party distribution partners in other markets. These international operations expose us and our subsidiaries and third- party distributors to a variety of risks including, without limitation, the following: • different, and in some cases more exacting and lengthy, regulatory approval processes, regulations and laws, ~~and~~ pricing and reimbursement systems, **and rebate requirements** applicable to us, our suppliers and distributors; • reduced or varied protection for intellectual property rights or difficulties enforcing our intellectual property rights and defending against third- party threats and intellectual property enforcement actions against us, our distributors, or any of our third- party suppliers; • pricing pressure or longer sales and payment cycles; • different competitive dynamics, including smaller market sizes, which we may not be able to fully appreciate before entering certain foreign markets; • a shortage of qualified sales personnel and distributors; • the challenges of managing foreign operations; • relative disadvantages compared to competitors with more recognizable names, longer operating histories and better established distribution networks and customer relationships; • political and economic instability, international terrorism and anti- U. S. sentiment, or the imposition of U. S. or international sanctions that could restrict or prohibit continued business; • changes in duties and tariffs, license obligations, importation laws and other non- tariff barriers to trade; • scrutiny of foreign tax authorities that could result in significant fines, penalties and additional taxes; • different cultural norms which may impact how business is conducted; • laws and business practices favoring local companies; • difficulties in maintaining consistency and compliance with our internal guidelines; • difficulties in enforcing agreements and collecting receivables through foreign legal systems; • risks of money laundering, bribery and corruption practices, off- label promotion or breach of sanction regulations by our personnel or distributors, which may be difficult for us to discover or prevent; • failures by our third- party partners to properly assist us with local guidance on operations, financial and other reporting, accounting, tax, payroll, legal and regulatory matters; and • costly and complex export requirements and restrictions, particularly relating to technology. If we experience any of these risks, our sales in non- U. S. jurisdictions may be harmed, our results of operations would suffer, and our reputation and business prospects would be negatively impacted. Additionally, we are exposed to changes in foreign currencies relative to the U. S. dollar, which are references to the differences between the foreign- exchanges rates we use to convert the financial results of our international operations from local currencies into U. S. dollars for financial reporting purposes. This impact of foreign- exchange rate changes is calculated based on the difference between the current period' s currency exchange rates and that of the comparable

prior period. Further, significant foreign exchange rate fluctuations resulting in a decline in the respective local currency may decrease our revenues and earnings from our foreign operations. As a result of our global operations, our revenue, gross margins, operating expense and operating income in some international markets have been and may continue to be affected by foreign currency fluctuations. If the quality or delivery of our products does not meet our customers' expectations, our reputation could suffer and ultimately our sales and operating earnings could be negatively impacted. As a manufacturer, we have addressed and must continue to address quality issues associated with our products, including in our engineering, design, manufacturing and delivery processes, as well as issues with third- party pharmaceuticals or components included in our products. Because our products are highly complex, the occurrence of ~~performance~~ **21 performance** issues may increase as we continue to introduce new products and rapidly scale up manufacturing to meet ~~22 increased~~ **increased** demand. Although we have established internal procedures to minimize risks that may arise from product quality issues, there can be no assurance that we will be able to eliminate or mitigate occurrences of these issues and associated liabilities. In addition, identifying the root cause of performance or quality issues, particularly those affecting third- party components or other elements, may be difficult, which increases the time needed to address quality issues as they arise and increases the risk that similar problems could recur. Finding solutions to quality issues can be expensive and we may incur significant costs, lost revenue or reputational damage in connection with, for example, shipment holds, product recalls and warranty or other service obligations. Quality issues can also impair our relationships with new or existing customers or result in product liability suits against us, which may be expensive to defend and could impact the reimbursement coverage of our products, our product liability insurance rates and / or our cash reserves in the event our existing insurance coverage is insufficient. The occurrence of any of the foregoing could harm our reputation as a producer of high- quality products and could adversely affect our business, financial condition or results of operations. Ophthalmic surgeons may not use our products if they do not believe they are safe, efficient, effective and preferable alternatives to other treatment solutions in the market or may use our products without being adequately trained, which could result in inferior clinical outcomes. We believe that ophthalmic surgeons will not use our products unless they conclude that our products provide a safe, efficient, effective and preferable alternative to currently available treatment options. Publications of clinical results by us, our competitors and other third parties may impact whether, and the degree to which, our products are used by physicians and the procedures and treatments those physicians choose to administer to their patients. If ophthalmic surgeons determine that any of our products are not sufficiently effective, efficient or safe, whether based on longer- term patient studies or clinical experience or unsatisfactory patient outcomes or patient injury, our sales would be harmed. Surgeons may base such determination on patient outcomes that are the result of other unqualified surgeons performing procedures for which they haven' t been trained. It is also possible that as our products become more widely used, latent defects could be identified, creating negative publicity and liability problems for us and adversely affecting demand for our products. If an increasing number of ophthalmic surgeons do not continue to adopt the use of our products, our operating and financial results will be negatively impacted. If we fail to manage our anticipated growth effectively, we may not be able to meet customer demand for our products and our business could suffer. Since the commercial launch of the iStent in 2012, we have seen significant period- to- period growth in our business, both organically and through transactions, and we must continue to grow in order to meet our business and financial objectives. However, continued growth creates numerous challenges, including, among others, new and increased responsibilities for our management team; increased competition; increased and, with respect to new products such as the iDose TR, uncertain product demand which could strain our manufacturing capacity or create product shortages; the management of an increasing number of customer, supplier and other relationships; increased pressure on our operating, financial and reporting systems; entry into new international territories with unfamiliar regulations and business approaches; and the need to hire, train and manage additional qualified personnel. If we fail to manage any of these challenges effectively, our business may be harmed. If we are unable to retain or recruit qualified personnel for growth, our business results could suffer. We have benefited substantially from the leadership and performance of our senior management and other key employees. For example, our chief executive officer, as well as other key members of our senior management, has experience successfully developing novel technologies and scaling early- stage medical device and pharmaceutical companies to achieve profitability. We also rely on our qualified sales representatives and on consultants and advisors in our research, operations, clinical and commercial efforts to grow our business, develop and commercialize new products and implement our business strategies. Our success will depend on our ability to retain our current management and key employees, consultants and advisors, and to attract and retain qualified personnel in the future, including by providing competitive compensation and benefit programs, flexible work arrangements, career advancement prospects and sufficient opportunities to develop leadership, managerial and other valuable skills. The loss of services of these personnel, which could occur without notice and without cause, could prevent or delay our growth plans and the ~~implementation~~ **22 implementation** of our strategic objectives, or divert management' s attention to seeking qualified replacements. Our U. S. ~~23 employees~~ **employees**, including our senior management, are not subject to non- competition agreements. Accordingly, the adverse effect of losing key personnel could be compounded by our inability to prevent them from competing with us. We have and may continue to enter into acquisitions, collaborations, in- licensing agreements, joint ventures, alliances or partnerships with third parties that could fail. We have and may continue to enter into acquisitions, collaborations, in- licensing agreements, joint ventures and partnerships in order to retain our competitive position within the marketplace, develop new products or expand into new markets. Examples include our acquisitions of DOSE Medical and Avedro, as well as our licensing of Santen' s PRESERFLO ® Microshunt ® (Preserflo MicroShunt), the Intratus drug delivery platform and the Atillaps, iVeena ~~and~~, Stuart ~~and~~ **and Ripple** pharmaceutical compounds and our collaboration agreement with Radius XR to market its wearable patient engagement and diagnostic system. However, we cannot assure you that we will be able to successfully complete any future acquisition we may pursue, or that we will be able to successfully integrate any acquired business, product or technology in a cost- effective and non- disruptive manner. Our future successes will depend, in part, on our ability to manage an expanded business, which may pose substantial challenges for

our management, such as increased costs and complexity. There can be no assurances that we will be successful in managing such expanded business or that we will realize the expected economies of scale, synergies and other benefits currently anticipated from recent or future acquisitions or strategic transactions. Additionally, these collaborations, joint ventures, and partnerships may fail to result in any commercialized product, including due to delays in or failures to obtain regulatory approvals, such as the failure to receive approval of the PreserFlo MicroShunt in the U. S., and could require us to invest a substantial amount of resources only to ultimately change regulatory strategies or to fail. In addition, these arrangements may be terminated before we are able to realize net sales to sufficiently cover the costs associated therewith, which could materially impact our business. We cannot assure you that any such transaction would result in the benefits expected from the transaction, including revenue growth, increased profitability or an enhancement in our business prospects. Further, pursuing acquisitions, collaborations, in- licensing agreements, joint ventures, alliances or partnerships with third parties, whether or not completed, is costly and time- consuming and could distract Company management from the operation of the business, which could negatively impact our operating results. Failure to protect our information systems against cybersecurity threats, cybersecurity incidents, service interruptions, or data corruption could materially disrupt our operations and adversely affect our business, operating results, or the effectiveness of our internal controls over financial reporting. The efficient operation of our global business depends on our information systems, including telecommunications, the internet, network communications, email and various computer hardware and software applications. We rely on our information systems to effectively manage sales and marketing data, accounting and financial functions, inventory management, product development tasks, clinical data, quality systems, customer service and technical support functions. Our information systems are vulnerable to damage or interruption from earthquakes, fires, floods and other natural disasters, terrorist attacks, power losses, computer system or data network failures, data corruption and security breaches or other cybersecurity incidents, some of which we have experienced and **which we continue to monitor and expect may experience in the future**. Cybersecurity incidents can include ransomware, computer denial- of- service attacks, worms, and other malicious software programs introduced to our computers and networks, including intrusions that are designed to evade detection for an extended period of time, phishing attacks, social engineering attacks, and efforts to discover and exploit any design flaws, bugs, security vulnerabilities or weaknesses, as well as intentional or unintentional acts by employees or other insiders with access privileges, intentional acts of vandalism or fraud by third parties and sabotage. Additionally, cybersecurity threats and the techniques used in cyberattacks change, develop and evolve rapidly, including from emerging technologies, such as advanced forms of **artificial intelligence (AI)** and quantum computing .

Further, use of AI by our employees, third- party service providers, strategic partners or other contractors or consultants, whether authorized or unauthorized, increases the risk that our intellectual property and other proprietary information will be unintentionally disclosed. While none of the cybersecurity incidents or service interruptions that we have experienced to date have had a material adverse impact on our business, financial condition or operations, the preventative measures we have implemented to date may not be sufficient to prevent, mitigate or offset a future incident that may materially and adversely impact us and the cybersecurity insurance we have obtained may or may not cover such an incident. In addition, some of our software systems are cloud- based data management ~~applications~~ **23applications**, hosted by third- party service providers whose security and information technology systems are subject to similar risks. The failure to protect either our or our service providers' information technology infrastructure could disrupt our entire operation, resulting in decreased sales, increased overhead costs, product shortages, or loss or misuse of intellectual property or proprietary, confidential, sensitive or personal ~~24information~~ **information**, all of which could have a material adverse effect on our reputation, business, financial condition and operating results or result in investigations, claims and administrative penalties by regulators. Our enterprise resource planning (ERP) system is integral to our ability to accurately and efficiently maintain our books and records, record transactions, and prepare our financial statements. Any disruptions or difficulties that may occur in connection with our ERP system (whether in connection with the regular operation, periodic enhancements or upgrades of such systems, or due to cybersecurity incidents) could adversely affect our ability to provide services, fulfill contractual obligations, file reports with the SEC in a timely manner, operate our business or otherwise affect our controls environment. If our independent registered public accounting firm determines that we have a material weakness in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the New York Stock Exchange, the SEC, or other regulatory authorities. Any of these events could have an adverse effect on our operating results and financial condition. Failure to comply with data privacy and security laws could have a material adverse effect on our business. We are subject to state, federal and foreign laws relating to data privacy and security in the conduct of our business, including state breach notification laws, the Health Insurance Portability and Accountability Act, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, the European Union' s General Data Protection Regulation (GDPR), the U. K. Data Protection Act and the U. K. GDPR, the California Consumer Privacy Act, and the California Privacy Rights Act, among others. These laws affect how we collect and use data of our employees, consultants, customers and other parties, including patients treated with our products. They may further restrict our transfer and use of such data, and may allow individuals to make requests or exercise rights that could limit use of data and require the expenditure of significant resources and time and effort to address. **In addition, as a result of the release and availability of AI technologies, including generative AI platforms, we have seen a global trend toward more comprehensive and refined regulation of AI that may impact our business, such as the EU AI Act, that are designed to ensure the ethical use, security, and privacy of AI and create standards for transparency, accountability, and fairness.** These laws, as well as similar laws being enacted by other states and countries, impose substantial requirements that involve the expenditure of significant resources and the investment of significant time and effort to comply. We also rely on third parties to host or otherwise process some of this data. In some instances, these third parties have experienced failures to protect data privacy. Our failure or the failure of these third parties to comply with these laws or prevent

security breaches of such data could result in significant liability, fines and penalties under applicable data privacy laws, cause disruption to our business, harm our reputation and have a material adverse effect on our business. We cannot be certain that our net operating loss tax carryforwards will be available to offset future taxable income. At December 31, 2023-2024, we had approximately \$ 463-527. 1-5 million, \$ 355-437. 3-0 million and \$ 9-6. 4-5 million of net operating loss (NOL) carryforwards for federal, state and foreign purposes, respectively. A portion-Portions of federal NOL carryforwards incurred prior to 2018 will expire annually, if unused, while \$ 257-322. 6-8 million will not expire but can only be used to offset 80 percent of federal taxable income. Additionally, portions of state and foreign NOL carryforwards will expire annually, if unused. At December 31, 2023-2024, we had federal and state R & D credit carryforwards of approximately \$ 43-48. 8-2 million and \$ 25-28. 0-6 million, respectively. Portions of federal and \$ 4. 4-6 million of state R & D credits will expire annually, if unused, while \$ 20-24. 6-0 million of state R & D credits carry forward indefinitely. Additionally, at as of December 31, 2023-2024, we had expect to be awarded a total of \$ 3. 0 million in California economic development credit carryforwards of \$ 3. 0 million. These economic development credits which can only be used to offset California taxable income and These credits begin to expire in 2028, if unused. We continue to provide a valuation allowance against a portion of these tax attributes because we believe that uncertainty exists with respect to their future realization. Utilization of these tax attributes may be subject to annual limitations-24limitations under IRC Sections 382 and 383 if we the Company experiences- experience an ownership change. To the extent available, we intend to use these NOL and credit carryforwards to offset future taxable income and / or income tax liabilities associated with our operations. There can be no assurance that we will generate sufficient taxable income in the carryforward-carry forward period to utilize the remaining tax attributes before they expire. 25Risks-- Risks Related to Our Indebtedness-The IndebtednessIf requirement that we incur future indebtedness, our obligation to service our the indebtedness could limit the cash flow available for our operations and have other consequences that could adversely affect our business, and we may not have sufficient cash flow from our business to pay our debt obligations. As of December 31, 2023, we had \$ 287. 5 million in principal amount of indebtedness as a result of the issuance of the Convertible Notes. We may also in the future incur additional indebtedness to meet future financing needs. Interest payments, fees, covenants and restrictions under agreements governing our current or future indebtedness ; including the indenture governing the Convertible Notes, could have significant consequences, including the following: impairing our ability to successfully continue to commercialize our current or future products; limiting our ability to obtain additional financing on satisfactory terms; increasing our vulnerability to general economic downturns, competition and industry conditions; requiring the dedication of a substantial portion of our cash flow from operations to service our indebtedness; and inhibiting our flexibility to plan for, or react to, changes in our business ; and diluting the interests of our existing stockholders if we issue shares of our common stock upon conversion of the Convertible Notes. The occurrence of any one of these events could have an adverse effect on our business, financial condition, operating results or cash flows and ability to satisfy our obligations under the indenture governing the Convertible Notes and any other indebtedness. Our ability to make scheduled payments of the principal and interest on, or to refinance the amounts payable under, our current or future indebtedness ; including the Convertible Notes, while still making necessary investments in our business, will depend on our operating and financial performance, including our ability to generate sufficient cash flow from operations, which may be subject to economic, financial, competitive and other factors beyond our control. If we are unable to generate such cash flow, we may be required to sell assets, restructure existing debt or obtain additional debt financing or equity capital on terms that may be onerous or highly dilutive. Our ability to refinance any future indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or secure desirable terms, which could result in a default on our debt obligations .The conditional conversion feature of the Convertible Notes, if triggered, may adversely affect our financial condition and operating results. In the event the conditional conversion feature of the Convertible Notes is triggered, as it was for the quarter ended September 30, 2023, holders of the Convertible Notes will have the option to convert the Convertible Notes at any time during specified periods. If one or more holders elect to convert their Convertible Notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock (other than paying cash in lieu of delivering any fractional share), we would be required to settle a portion or all of our conversion obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders of the Convertible Notes do not elect to convert their Convertible Notes, we could be required under applicable accounting rules to reclassify all or a portion of the outstanding principal of the Convertible Notes as a current rather than long-term liability, which would result in a material reduction of our net working capital. We may not have the ability to raise the funds necessary to settle conversions of the Convertible Notes in cash or to repurchase the Convertible Notes upon a fundamental change, and our future debt may contain limitations on our ability to pay cash upon conversion or repurchase of the Convertible Notes. Noteholders may require us to repurchase their Convertible Notes upon the occurrence of a fundamental change at a repurchase price equal to 100 % of the aggregate principal amount of the Convertible Notes to be repurchased, plus accrued and unpaid interest, if any, to, but excluding, the fundamental change repurchase date. In addition, upon conversion of the Convertible Notes, unless we elect to deliver solely shares of our common stock to settle such conversion (other than paying cash in lieu of delivering any fractional share), we will be required to make cash payments in respect of the Convertible Notes being converted. However, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of the Convertible Notes surrendered or Convertible Notes being converted. In addition, our ability to repurchase the Convertible Notes or to pay cash upon conversions of the Convertible Notes may be limited by law, by regulatory authority or by agreements governing our future indebtedness. Our failure to repurchase Convertible Notes, or to pay any cash payable on future conversions of the 26Convertible Notes as required by the indenture governing the Convertible Notes would constitute a default under the indenture governing the Convertible Notes, which event, or the occurrence of the fundamental change itself, may lead to a default under any future credit facility or other agreements governing our future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the

indebtedness and repurchase the Convertible Notes or make cash payments upon conversions thereof. The capped call transactions may affect the value of our common stock, and subject us to counterparty risk. In connection with the issuance of the Convertible Notes, we entered into capped call transactions with certain option counterparties. The capped call transactions ~~initially cover covered~~, subject to customary adjustments, the number of shares of common stock initially underlying the Convertible Notes. The capped call transactions ~~are were~~ expected generally to reduce the potential dilution of our common stock upon any conversion of the Convertible Notes or at our election (subject to certain conditions), offset any cash payments we ~~are would be~~ required to make in excess of the aggregate principal amount of converted Convertible Notes, as the case may be, with such reduction or offset subject to a cap. We have been advised that the option counterparties or their respective affiliates have established initial hedges of the capped call transaction, and may modify their hedge positions by entering into or unwinding various derivative transactions with respect to our common stock and / or purchasing or selling our common stock or other securities of ours in secondary market transactions prior to the maturity of the Convertible Notes ~~(and are likely to do so on each exercise date of the capped call transactions, which are expected to occur during the 40 trading day period beginning on the 41st scheduled trading day prior to the maturity date of the Convertible Notes, or following any termination of any portion of the capped call transactions in connection with any repurchase, redemption or early conversion of the Convertible Notes)~~. **This In December 2024, we unwound a portion of capped call transactions corresponding to fifty percent of the number of shares of the Company's common stock initially underlying the Convertible Notes. However, the remaining capped call transaction may still modify their hedge positions and such hedge modification** activity could impact the market price of our common stock. The option counterparties to the capped call transactions are financial ~~Institutions institutions~~, and we are subject to the risk that any or all of them might default under the capped call transactions. Our exposure to the credit risk of the option counterparties is not secured by any collateral. Past global economic conditions have resulted in the actual or perceived failure or financial difficulties of many financial institutions. If an option counterparty becomes subject to insolvency proceedings, we will become an unsecured creditor in those proceedings with a claim equal to our exposure at that time under the capped call transactions with such option counterparty. Our exposure will depend on many factors but, generally, an increase in our exposure will be correlated to an increase in the market price ~~subject to the cap and in the volatility~~ of our common stock ~~- In addition, upon a default by subject 25to the cap an and in the volatility of~~ option counterparty, we may suffer more dilution ~~than we currently anticipate with respect to~~ our common stock. We can provide no assurances as to the financial stability or viability of the option counterparties. **Risks Related to Our Regulatory Environment Healthcare legislative reform measures and changes in U. S. and international trade policies may have a material adverse effect on our business and results of operations. The current administration has enacted or proposed legislative, administrative and executive actions and regulatory changes that could affect our ability to profitably sell our commercialized products or products for which we obtain marketing approval. For example, the current administration previously enacted several executive actions that could impose pressures on and create uncertainty surrounding the U. S. federal government's budget and potential changes in budgetary priorities and spending levels. Such pressures and uncertainty could adversely affect staffing levels and the funding for the FDA and as a result, prevent or delay marketing approval of our current or future pipeline products, restrict or regulate post- approval activities and affect our ability to profitably sell any product for which we obtain marketing approval, each of which may negatively impact our business. Further, there have been, and may continue to be, legislative and regulatory proposals at the U. S. federal and state levels and in foreign jurisdictions directed at broadening the availability and containing or lowering the cost of healthcare including plans announced by the current administration to reform the U. S. pharmaceutical pricing system significantly through rulemaking and executive orders. In addition, existing legislation aimed at patient affordability in the United States such as the Patient Protection and Affordable Care Act may be repealed or replaced. The continuing efforts of the government, insurance companies and third- party payors to contain or reduce costs of healthcare may adversely affect our ability to set prices for our products that would allow us to achieve or sustain profitability. In addition, governments may impose price controls on any of our products, which may adversely affect our future profitability. These risks may also impact the development decisions we make with respect to our pipeline products. Additionally, the U. S. government has recently made statements and taken certain actions that have created significant uncertainty about the future relationship between the U. S. and various other countries with respect to trade policies, treaties, government regulations and tariffs, which may lead to the imposition of tariffs and export control restrictions affecting certain products manufactured in certain other countries. As a result of these statements and actions, we are exposed to the possibility of product supply disruption and increased costs and expenses. While we cannot predict the likelihood, nature or extent of the potential impact, unfavorable government policies on international trade, such as export controls, or tariffs, may increase the cost of manufacturing our commercialized products or developing our pipeline products, affect the demand for our products (if and once approved), or restrict our access to raw materials and components used in the manufacture of our current products and the development of our future products, each of which could negatively impact our financial condition and results of operations.** Our business, products and processes are subject to extensive regulation both in the U. S. and abroad and it can be costly to comply with these regulations. Any failure to adhere to applicable regulations could harm our business, financial condition and operating results. Our medical devices, drugs, drug / device combination products and other products are subject to extensive government regulation in the U. S. by the FDA, state regulatory authorities and foreign regulatory authorities in the countries in which we conduct business. These regulations relate to, among other things, approval or clearance of our products for sale, R & D, labeling, advertising, promotion, pricing and discounts, recordkeeping, reporting, import and export, post- approval studies and the sale and distribution of our products. See Item 1, Business, " Government Regulation – U. S. Regulation & Reimbursement " and " International Regulation & Reimbursement " in this Annual Report for additional information. Our failure to comply with applicable regulatory requirements could result in enforcement action by the

FDA, or state or foreign regulatory authorities, which may include, among other things, warning letters, fines, injunctions, recalls, refusals to grant or delays in granting requests, civil fines and penalties, operating restrictions, withdrawal of approvals and even criminal prosecution. The process of obtaining clearances or approvals to market our products can be expensive and lengthy, and we cannot guarantee that our current products will receive clearance or approval for additional indications or that our future products will receive clearance or approval on a timely basis, or without restrictions, if at all. Additionally, based upon a recent FDA determination, our pipeline products ~~26~~ **products** that are determined to be drug- device combination products, such as our iDose TR product, ~~will require~~ **requires** review and coordination by each of FDA's drug and device centers prior to approval, which may delay approval **of our future products**. In some instances, we or our partners have pursued, and may in the future pursue, a regulatory clearance or approval that proves unsuccessful, such as the FDA's recent failure to approve the PreserFlo Microshunt in the U. S. and our determination to conduct a second pivotal confirmatory study of our Epioxa pharmaceutical therapy based on recommendations from the FDA in pre- NDA submission meetings. When this occurs, the time and financial resources required to obtain FDA or other regulatory approval may substantially increase or new competitive products could reach the market faster than our product candidate, which could materially adversely impact our competitive position and prospects. ~~We cannot assure you that we will receive the requisite approvals to sell our product candidates on our anticipated timeline or at all.~~ Before we can obtain regulatory approval for any product candidate, we may have to undertake complex, time- consuming and expensive clinical testing in humans to demonstrate safety and efficacy, the outcomes of which are inherently uncertain and may never result in approved products or commercial sales. We have experienced in the past, and could experience in the future, delays in the commencement or completion of clinical trials or testing that could significantly affect our product development costs. We do not know whether planned clinical trials will begin on time, need to be redesigned, enroll an adequate number of patients in a timely manner or be completed on schedule, if at all, or be deemed insufficient by the FDA, which may require additional lengthy, time- consuming and expensive trials, which would further delay approval. We may suffer significant setbacks in clinical trials, even after earlier trials showed promising results, and failure can occur at any time during the clinical trial process. We, the clinical trial investigators, the independent review board overseeing the trial, the FDA, or another regulatory authority may suspend, delay or terminate clinical trials at any time due to a number of factors, including failure to conduct the trial in accordance with applicable regulatory requirements or trial protocols, failure to demonstrate a benefit from using the product, lack of sufficient funding, medical device product malfunctions, adverse events, or to avoid exposing trial participants to unacceptable health risks. Any delay or failure in clinical trials would delay or prevent our ability to obtain necessary regulatory approvals, which would have a material adverse effect on our business, financial condition and prospects. ~~If As part of the PMA regulatory application and approval process, the FDA will generally conduct a pre-approval inspection of the applicant or our its facilities, or those of our~~ **third- party manufacturers** ~~or suppliers, fail ' manufacturing facilities to meet ensure compliance with the FDA's Quality System Regulation (QSR) for medical devices or current Good Manufacturing Practice (cGMP) regulations for drug and combination products, such as our iDose TR product. If our facilities, or those of our third- party manufacturers or suppliers, fail to meet the QSR or cGMP regulations, as applicable, or other standards required by the FDA, we could experience a delay in obtaining the necessary regulatory clearances or approvals to commercialize our pipeline products, which could have a material adverse effect on our business and financial condition and results. We Even after we have obtained the proper regulatory clearance or approval to market a product, we have ongoing responsibilities under FDA regulations and applicable foreign laws and regulations. We and we may also be required to seek additional regulatory approvals to modify our approved products or their manufacturing processes or indications, which may entail significant time and expense. We and our suppliers are subject to extensive post-marketing regulatory requirements including post- marketing studies, and failure to comply with applicable requirements in a timely manner could subject us to enforcement actions, including recall or product approval withdrawals. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections by the FDA. Other post- market requirements on our products include establishment registration and device listing, quality system and good manufacturing requirements, reporting of adverse events and device malfunctions, product tracing, reporting of corrections and removals (recalls), labeling requirements, and promotional restrictions. Under FDA See Item 1, Business, "Government regulations- Regulation – U , combination products are subject to the quality system and good manufacturing requirements applicable to both drugs and medical devices. S. Regulation & Reimbursement – Post- Our products could malfunction, cause unexpected adverse events, or experience performance problems that require review and possible corrective action by us or a component supplier, including a recall or market Market withdrawal Regulation " in this Annual Report for additional information. Any Additionally, any recall or product withdrawal, whether required by the FDA or, another regulatory authority or initiated by us, could harm our reputation with customers, cause us to incur significant expense and negatively affect our sales. 28 In In addition, our promotional materials, sales techniques, pricing programs and training methods must comply with FDA and other applicable laws and regulations , including the prohibition of the promotion of a drug or medical device for a use that has not been cleared or approved by the FDA or other regulatory authorities, also known as an " off- label " use. The FDA or other regulatory authorities may limit the indications for use of our products, thereby restricting our ability to promote the drug or device. Physicians may use our products, particularly newly- approved products, off- label or in combination with other products that are not indicated or appropriate, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA determines that our promotional materials, sales techniques, pricing programs or training constitutes promotion of an off- label use or encourages over- utilization of our products or use of our products in combinations that are not indicated or appropriate, it could request that we modify our materials, techniques, programs or training or subject us to enforcement actions. We 27 We are subject to healthcare fraud and abuse, anti-kickback, false claims and transparency laws and regulations, among others, which are enforced by federal, state and international governments with respect to our marketing, training, customer arrangements, discount, rebate and pricing~~

programs, product bundling, financial arrangements with physicians, patient assistance programs, reimbursement support services, and other practices. See Item 1, Business, “ Government Regulation – U. S. Regulation & Reimbursement ” and “ International Regulation & Reimbursement ” contained in this Annual Report **on Form 10-K** for additional information about the laws and regulations which apply to us. The U. S. Department of Justice has increased its scrutiny of interactions between manufacturers and healthcare providers, as well as various patient, product and reimbursement support programs and speaker bureaus, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Although we try to structure our arrangements within available safe harbors whenever possible, we may nevertheless become subject to government scrutiny or investigation. Violations may result in civil monetary penalties, criminal penalties, and exclusion from participation in government healthcare programs, including Medicare and Medicaid, all of which would have an adverse effect on our business. We are also subject to compliance with various anti- bribery laws and regulations, including the U. S. Foreign Corrupt Practices Act, the U. K. Bribery Act, and similar anti- bribery laws in other jurisdictions, which generally prohibit companies and their agents from making bribes or other improper payments to officials for the purpose of obtaining or retaining business. We are also subject to limitations on trade with persons in sanctioned countries. Our sales in international markets increase the inherent risks of encountering such issues. While our employees, distributors and agents are required to comply with these laws and regulations, no assurance can be given that our training efforts and internal policies and procedures will prevent violations of these laws. Any actual or alleged violations of these laws and regulations could subject us to government investigations, criminal sanctions, severe fines and penalties that could have a material adverse impact on our reputation, financial condition, results of operations and cash flows. The scope and enforcement of each of the laws applicable to our business and products is uncertain and subject to rapid change in the current environment of healthcare reform. ~~If our operations are found to be in violation of any of the government regulations that apply to us, we may be subject to civil and criminal penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in federal and state healthcare programs and the curtailment or restricting of our operations, any of which could harm our ability to operate our business and our financial results.~~ Responding to a government investigation is time and resource intensive, and may cause harm to our business and reputation even if we are able to successfully defend against it. Additionally, resolution of any such investigation may require agreement to onerous corporate integrity agreements or other compliance or reporting requirements, which may negatively affect our business. Legislative or regulatory reform of the healthcare system could hinder or prevent our products’ commercial success. In the U. S. and in certain states and foreign jurisdictions, there have been a number of legislative and regulatory proposals and adoptions to change the healthcare systems in ways that could impact our ability to sell our products profitably, if at all. In addition, new regulations and interpretations of existing healthcare statutes and regulations are frequently adopted and we may not be able to comply with the changed laws, they could increase the cost of manufacturing, marketing or selling our product, could make approvals of pipeline products more difficult or prevent us from selling at all. We expect there will continue to be a number of legislative and regulatory changes to the U. S. health care system that could significantly change the statutory provisions governing the regulatory approval, manufacture and ~~29marketing~~ **marketing** of regulated products or the reimbursement thereof and may impose additional costs or lengthen review times of planned or future products. It is also difficult to predict whether and how the policies and priorities of a new administration could materially impact the regulation governing our products. **In 2017 A new U. S. administration may propose policy changes that create additional uncertainty for our business, such as changes to the level of scrutiny to enforce the 340B drug pricing program (340B program) non-compliance, new price restrictions on products we sell to Medicaid, Medicare or other government purchasers, or other regulatory changes impacting reimbursement or competitive dynamics in the markets in which we operate. The extent to which such policy changes impact the healthcare regulatory environment remains uncertain and could materially impact our business and operations. Additionally, in its June 2024 decision in Loper Bright Enterprises v. Raimondo (the “ Loper ”), the U. S. Supreme Court overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies’ reasonable interpretations of ambiguous federal statutes. The Loper decision could result in additional legal challenges to regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA and CMS. Further, the Loper decision may result in increased regulatory uncertainty, inconsistent judicial interpretations and other impacts to the agency rulemaking process. We cannot predict which 28additional measures may be adopted or the impact of current and additional measures on the marketing, pricing and demand for our products, which could have a material adverse effect on our business, financial condition and results of operations. We are also subject to** the EU adopted’ s Medical Devices Regulation 2017/745 (MDR), which ~~could result~~ repealed and replaced the Medical Device Directive (MDD). MDR went into effect in **substantial** May 2021 and provides for stricter controls of medical devices than did MDD. Under provisions that govern the transition from MDD to MDR, qualifying medical devices with notified body certificates issued under the MDD prior to May 2021 may continue to be marketed and sold through 2028. After the expiration of any applicable transitional period, only devices that have been CE marked under MDR may be placed on the market in the EU. Additionally ~~--~~ **additional costs of compliance. In addition**, the bio-activated therapy used with our **products** crosslinking device to treat keratoconus in international markets, which is currently classified as a medical device in the EU and certain other countries, ~~could be reclassified in international markets as a drug product,~~ which would impose an entirely new regulatory framework on us and our contract manufacturers ~~for this product,~~ and compliance may prove costly and difficult or may not be achievable at all. Our failure, or the failure of our contract manufacturers, to obtain CE marks for all of our products under MDR on a timely basis, or to comply with MDR or applicable European Medicines Agency regulations regarding drug products, could restrict our ability to sell our products in the EU or other parts of the world, which would have a material adverse effect on our business and financial results. From time to time, we increase the prices of our products, as we have **previously** done with our Photrexa therapies. Drug pricing by pharmaceutical manufacturers is subject to federal and state reporting requirements and is currently, and is expected to continue to be, under

close scrutiny, including with respect to manufacturers that increase the price of products after acquiring those products from other companies. In some cases, such scrutiny has resulted in congressional inquiries and federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturers' patient support programs, and reform government program reimbursement methodologies for products. Although our price increases have been based upon third party studies of the projected economic value of our products to the healthcare system, they may still become subject to such scrutiny. As a condition of having our ~~recently approved~~ iDose TR product covered under certain federal healthcare programs such as Medicare and Medicaid, we are required to participate in the ~~Medicaid Drug Rebate Program (MDRP)~~ with respect to all of our pharmaceutical products, which requires us to calculate and report certain pricing metrics to the government, comply with certain pricing limitations ~~any and~~ pay a rebate to each state Medicaid program for our covered products based on utilization of our products by Medicaid beneficiaries. Any company that participates in the MDRP also must participate in the 340B ~~drug pricing program (the "340B program")~~. The 340B program, which is administered by the Health Resources and Services Administration, requires participating companies to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for covered outpatient drugs. The 340B ~~program~~ ceiling price is calculated using a statutory formula, which is based on pricing data calculated under the MDRP. Additionally, the U. S. Inflation Reduction Act of 2022 (~~IRA~~), which is designed to, among other things, have a direct impact on drug prices and reduce drug spending by the federal government, requires drug manufacturers to pay rebates to Medicare if they increase prices faster than inflation for certain drugs used by Medicare beneficiaries. The expansion of inflation-based rebates may complicate our pricing strategies. **See Item 1, Business, "Government Regulation – U. S. Regulation & Reimbursement" in this Annual Report for more information on the MDRP.** To the extent applicable, these and other similar legislation or regulations will reduce the prices we can charge, and impact the rebate amount we must pay, on sales of our products subject to that act, particularly on sales to our customers if they qualify as covered entities eligible to receive the discounted 340B ceiling price. Compliance with these laws and programs may reduce our net sales, and could require significant resources, which would reduce our profitability. ~~Additionally~~ **Further**, we cannot predict how our participation in, or how future CMS guidance or rules governing, MDRP will affect our profitability (including the potential for increases in our overall Medicaid rebate liability and the obligation to charge reduced prices to covered entities). Any changes to the limitations, calculations, or scope of these programs could negatively impact the results of our operations. **Additionally, pricing and rebate calculations are complex and often subject to interpretation by the manufacturer, governmental agencies and courts. A manufacturer that becomes aware that its Medicaid reporting for a prior was incorrect or has changed as a result of a recalculation of pricing data is obligated to resubmit corrected data up to three years after the data was originally due. Restatements and recalculations may result in an overage or shortfall in our rebate liability for prior periods, and may affect our 340B ceiling price and therefore liability under the 340B program.** If we cannot sell our products profitably, whether due to our own inability to comply with, or the inability of other economic operators in our supply chain to qualify under, any legislative reform or pricing programs, our business would be harmed. In addition, any change in the laws or regulations that govern the clearance and approval processes ~~relating to~~ **relating to** our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products. ~~30Inadequate~~ **Inadequate** or inconsistent reimbursement for our products may adversely impact our business. Our ability to successfully commercialize and achieve market acceptance of our products and compete against other therapies designed to address the same disease states depends in significant part on adequate financial coverage and reimbursement from third party payors, including governmental payors (such as the Medicare and Medicaid programs in the U. S.), managed care organizations and private health insurers. See Item 1, Business, "Government Regulation – U. S. Regulation & Reimbursement" and "International Regulation & Reimbursement" contained in ~~this our~~ Annual Report for additional information. Payors continually review the clinical evidence for new therapies and can change their coverage policies without notice or deny payment if the product was not used in accordance with the payor's coverage policy. Therefore, coverage for our products can differ significantly from payor to payor. ~~In addition, payors continually review new therapies for possible coverage and can, without notice, deny coverage for these products and procedures.~~ As a result, the coverage determination process is often time-consuming and costly and requires us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage will be obtained or will be maintained once it is obtained. In addition to uncertainties surrounding coverage policies, there are uncertainties regarding appropriate reimbursement for the procedures associated with **certain of** our new products like iAccess, a precision blade, iPRIME, a viscoelastic delivery system, and iStent infinite **and iDose TR**, as well as sporadic volatility in reimbursement levels of existing products, including our Photrexa therapy and the procedures associated with our existing products, such as our iStent family of products. For example, in 2022 the CMS' payment rates significantly lowered the Medicare physician fee payment rates and slightly lowered the Medicare facility fee payment rates related to the implantation of trabecular bypass stents, such as our iStent family of products, in conjunction with cataract surgery, furnished in the ambulatory surgery center (ASC) setting, which we believe disrupted traditional customer ordering patterns and resulted in **certain of** our customers' ~~trialing and~~ utilization of competitive products, causing reduced glaucoma sales volumes in the U. S. in 2022 and 2023. Additionally, the facility fee payment rates for the standalone procedure that hospitals and ambulatory surgery centers will use with Glaukos' iStent infinite product ~~were lower than anticipated for 2022 and were not significantly modified by CMS for 2023 facility fee payment rates.~~ ~~While CMS' 2024 Medicare payment rates increased facility fee payment rates related to the implantation of trabecular bypass stents,~~ **which had** such as our iStent family of products, both in conjunction with cataract surgery and as a standalone procedure, in both the ASC and hospital setting, we expect the reduced physician and facility fee payment rates to have an adverse impact on procedural iStent family product volumes, ~~in conjunction with cataract surgery and on a stand-~~ **and** alone basis, in 2024 as well as on our U. S. ~~combo- cataract glaucoma~~ revenues, gross profit, and net income. The demand for, and the profitability of, our products could be materially harmed if the Medicaid program,

Medicare program, other healthcare programs in the U. S. or elsewhere, or third party commercial payors in the U. S. or elsewhere, deny reimbursement for our products, limit the indications for which our products will be reimbursed, are unclear on appropriate reimbursement codes or provide reimbursement only on unfavorable terms. For example, in June 2023 five MACs, which set physician fee payment rates for products covered by temporary CPT Category III codes, published proposed local coverage determinations (LCDs) that deemed certain ophthalmic procedures, including the procedures using our iAccess and iPRIME products, investigational and therefore not covered by Medicare and not reimbursed, which LCD was ultimately adopted and then reversed by these MACs. **This non- coverage determination was not included in the proposed LCDs subsequently published by the five MACs in April 2024 and finalized in November 2024. Additionally, the physician fee payment rates for the procedures using our iDose TR product will be determined by the MACs, the majority of which have not yet published this rate.** Also, when procedures associated with our products transition from temporary CPT Category III codes to permanent CPT Category I codes, the physician and facility reimbursement levels associated with the procedures using these products could be decreased, such as the decreased payment rates for procedures using our iStent- related products, in conjunction with cataract surgery, established by CMS for 2022 and 2023, as discussed above. Even when a permanent billing code has been assigned to a product, there is no guarantee that coverage will be provided. If we are unable to maintain our existing codes or obtain new permanent codes for procedures using our products, use existing codes for new products or obtain new reimbursement codes for our products in development, we may be subject to significant pricing pressure, that could harm our results of operations, financial condition and prospects. In the foreign markets in which we operate, different pricing and reimbursement systems, could result in lower reimbursement, harming our ability to operate our business. We cannot predict to what extent current global economic conditions may disrupt healthcare systems and access to our products or result in a widespread loss of individual health insurance coverage due to unemployment, a shift from ~~commercial~~ **30commercial** payor coverage to government payor coverage, or an increase in demand for patient assistance or free drug ~~31programs~~ **programs**, any of which could adversely affect our net revenue. In addition, payers consistently engage in cost containment efforts, which could result in decreased reimbursement levels for prescription drugs and the imposition of prior authorization for the use of our products. We cannot predict actions that third party payors may take, including limiting access to or the level of reimbursement for our products or refusal to provide any approvals or coverage. Risks Related to Our Intellectual Property If we are unable to adequately protect our intellectual property, our competitors and other third parties could develop and commercialize products similar or identical to ours, which would substantially impair our ability to compete. Our success and ability to compete depends significantly upon our ability to obtain, maintain and protect our proprietary rights and licensed intellectual property rights to the technologies and inventions used in or embodied by our products. We rely on a combination of patents and trademark rights, and to a lesser extent on trade secrets and copyrights, together with licenses and nondisclosure agreements to protect our technologies. These legal means, however, afford only limited protection and may not adequately protect our business. We also have not pursued or maintained, and may not pursue or maintain in the future, patent protection for our products in every country or territory in which we sell or will in the future sell our products. In addition, we cannot be sure that any of our pending patent applications or pending trademark applications will issue or issue in a form that will be advantageous to us. Despite our efforts, we cannot guarantee that we will be able to adequately protect our proprietary rights, which could substantially impair our ability to compete. Our patents may be challenged and held invalid or we may be unable to extend the protection on products with expiring patents. Moreover, our competitors may independently develop equivalent knowledge, methods and know- how. Competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. Further, although it is our policy to require each of our employees, consultants and any other parties who may be involved in the development of intellectual property on our behalf to execute proprietary information and inventions agreements, we may be unsuccessful in doing so with each party who in fact develops intellectual property that we regard as our own. The relevant assignment provisions may not be self- executing or may be breached, resulting in ownership disputes and / or litigation. We have many foreign patents and patent applications, and expect to pursue patent protection in the most significant markets in which we do business. The laws of other countries in which our products are or may be sold may not protect our product offerings and intellectual property to the same extent as U. S. laws, if at all. Many companies have encountered significant difficulties in obtaining, protecting and defending such rights in international markets. In addition, many countries limit the enforceability of patents against other parties, including government agencies or government contractors. In these countries, the patent owner may have limited remedies, and certain countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to other parties. We also may be unable to protect our rights in trade secrets and unpatented proprietary technology in these countries. If we encounter such difficulties or are otherwise precluded from effectively protecting our intellectual property rights in these countries, our business, financial condition and results of operations could be substantially harmed. We may not be able to accurately estimate or control our future operating expenses in relation to obtaining, enforcing and / or defending intellectual property, which could lead to cash shortfalls. Our operating expenses may fluctuate significantly in the future as a result of the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other patent related costs, including litigation costs and the results of such litigation or costs associated with administrative proceedings and the results of such proceedings. We have been and may in the future become involved in patent and other intellectual property litigation or administrative proceedings relating to our intellectual property rights, which could be costly, time consuming and unsuccessful and could interfere with our ability to successfully commercialize our products. Intellectual property rights are essential to our business. We have asserted and may in the future need to assert claims of infringement against third parties to protect our rights, or to invalidate or challenge the intellectual property ~~rights~~ **31rights** of a third party, including those rights owned by our competitors. Additionally, third parties could assert ~~32infringement~~ **infringement** or misappropriation claims against us with respect to our

current or future commercial products and seek to invalidate one or more of our patents or trademarks. Such claims could arise in situations where certain employees, consultants or contractors were previously, or are currently, employed by other medical device, biotechnology or pharmaceutical companies, including our competitors or potential competitors; we may be subject to claims that we or these individuals have, inadvertently or otherwise, misappropriated the intellectual property or disclosed the alleged trade secrets or other proprietary information, of these other employers. There is no guarantee that we would be successful enforcing or defending our intellectual property rights in court. A court could hold that some or all of our asserted intellectual property rights are not infringed, or could invalidate our rights, hold our rights unenforceable, or substantially narrow the scope of protection. Further, we could be prohibited from manufacturing or selling our products or a court could order us to pay substantial compensatory damages as well as other penalties and fines. Any such adverse result would undermine our competitive position. Regardless of the final outcome, any litigation to enforce our intellectual property rights in patents, copyrights, trade secrets or trademarks is highly unpredictable and could result in substantial costs and diversion of resources, which could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Common Stock

Anti-takeover provisions in our Charter and Bylaws and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management and limit the market price of our common stock. Provisions in our Restated Certificate of Incorporation (Charter) and amended and restated bylaws (Bylaws) may have the effect of delaying or preventing a change of control or changes in our management. Our Charter and Bylaws include provisions that:

- authorize our board of directors to issue, without further action by the stockholders, up to 5,000,000 shares of undesignated preferred stock;
- require that any action to be taken by our stockholders be affected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders may be called only by our board of directors, the chairman of the board of directors, the chief executive officer or the president;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- divide our board of directors into three classes, with each class serving staggered three year terms;
- provide that our directors may be removed only for cause by a supermajority vote of our stockholders;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- specify that no stockholder is permitted to cumulate votes at any election of directors; and
- require a supermajority vote of the stockholders and a majority vote of the board to amend certain of the above-mentioned provisions and our Bylaws.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us. The exclusive forum provisions in our organizational documents could limit our stockholders' ability to bring a claim in a judicial forum that it finds favorable for disputes with the Company or its directors, officers or other employees. Our Charter and Bylaws provide that, unless the Company consents in writing, the Court of Chancery of the State of Delaware is the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the **32** Company, ~~(ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any director, officer or 33~~