



2022  
**Annual  
Report**

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549  
**FORM 10-K**

(Mark one)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2022

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from: to

Commission File No. 001-37463

**GLAUKOS CORPORATION**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of incorporation or organization)

**33-0945406**  
(I.R.S. Employer Identification No.)

**One Glaukos Way**  
**Aliso Viejo, California**  
(Address of principal executive office)

**92656**  
(Zip Code)

**(949) 367-9600**  
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	GKOS	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: **None.**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files) Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company or an emerging growth company. (See definitions of "large accelerated filer", "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act).

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐ Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

As of June 30, 2022, the last business day of the registrant's most recently completed second quarter, the aggregate market value of common stock held by non-affiliates of the registrant, based on the closing sales price for the registrant's common stock as reported on The New York Stock Exchange, was \$2,067 million.

The number of shares of the Registrant's common stock outstanding as of February 22, 2023 (latest practicable date) was 47,878,462 shares.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Registrant's Proxy Statement for the 2023 Annual Meeting of Stockholders are incorporated herein by reference in Part III of this Annual Report on Form 10-K to the extent stated herein. Such Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after the close of the registrant's fiscal year ended December 31, 2022.

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We use *Glaukos*, our logo, *iStent*, *iStent inject*, *iStent infinite*, *iPrism*, *iDose*, *iPRIME*, *MIGS*, *Avedro*, *Photrex*, *iLink*, *KXL*, *Epioxa*, *iLution*, *Retina XR* and other marks as trademarks. This report contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this report, including logos, artwork and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities’ trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

References throughout this document to the “Company,” “we,” “us,” “our,” or “Glaukos” refer to Glaukos Corporation and its consolidated subsidiaries.

## **SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA**

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act). All statements other than statements of historical or current facts in this report or referred to or incorporated by reference into this report are forward-looking statements. In some cases, you can identify forward-looking statements by the following words: “may,” “will,” “could,” “would,” “should,” “expect,” “intend,” “plan,” “anticipate,” “believe,” “estimate,” “predict,” “project,” “potential,” “continue,” “ongoing” or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. Forward-looking statements in this Annual Report on Form 10-K include statements regarding: future operations; expected operating results and financial performance; the Company’s strategy for growth; product development activities; regulatory approvals, including timing and likelihood of success; market position and expenditures, and may be included under Item 1 - “Business,” Item 1A - “Risk Factors,” Item 7 - “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Annual Report on Form 10-K contain forward-looking statements. These forward-looking statements are based on management’s beliefs and assumptions based on the information currently available to management. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report on Form 10-K, we caution you that these forward-looking statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements.

You are urged to carefully review the disclosures we make concerning the risks we face and other factors that may affect the outcome of our forward-looking statements and our business and operating results, including the risks set forth in the “Risk Factors” section of this Annual Report on Form 10-K. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report on Form 10-K will prove to be accurate, and actual results may differ materially from those expressed or implied by the forward-looking statements. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans or that any of our expectations will occur in any specified time frame, or at all. You are therefore cautioned not to place undue reliance on the forward-looking statements included in this Annual Report on Form 10-K, which speak only as of the date of this document. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

This Annual Report on Form 10-K contains market data and industry forecasts that were obtained from industry publications. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such information. Although we believe that the industry publications on which the market and industry statements are based are reliable and we are not aware of any misstatements regarding any market data or industry forecasts presented herein, we have not independently verified any of the third party information.

## **WEBSITE REFERENCES**

In this Annual Report on Form 10-K, we make references to our website at [www.glaukos.com](http://www.glaukos.com). References to our website through this Form 10-K are provided for convenience only and the content on our website does not constitute a part of, and shall not be deemed incorporated by reference into, this Annual Report on Form 10-K.

## **PART I**

### **ITEM 1. BUSINESS**

#### **Overview**

Glaukos is an ophthalmic medical technology and pharmaceutical company focused on developing novel therapies 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, and continue to develop a portfolio of technologically distinct and leverageable platforms to support ongoing pharmaceutical and medical device innovations. Products and product candidates for 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 with various treatment options.

Our commercial solutions and development-stage product candidates include:

- MIGS products that primarily involve the insertion of a micro-scale device or drug delivery system designed to reduce intraocular pressure (IOP) by restoring the natural aqueous humor outflow pathways for patients suffering from glaucoma;
- 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 dry eye, presbyopia, glaucoma and other ocular surface diseases and disorders; and
- proprietary micro-invasive, bio-erodible 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 AMD, DME, and RVO;

#### **Impact of the Current Global Economic Environment**

The global economy and the regional economies that we serve have recently experienced significant volatility including inflation, supply shortages or delays, geopolitical developments, changes in supply and demand, labor shortages and turnover, natural disasters, higher energy costs, health epidemics or pandemics (including the COVID-19 pandemic), currency fluctuations, governmental actions such as mandatory shutdowns, and other conditions which have led to disruptions in commerce and pricing stability. The duration and scope of these conditions cannot be predicted, and therefore, it is uncertain what long-term impacts these economic pressures may have on our business.

While the COVID-19 pandemic materially impacted the global demand for our products, we have seen a general return toward more normalized levels for cataract and keratoconus procedures, with periodic volatility in certain geographies in which we operate, through December 31, 2022. Nevertheless, our business may be impacted by future developments, including any subsequent outbreaks or new variants of the COVID-19 virus, or other future health crises, which may require re-closures or other preventative measures. Additionally, the COVID-19 pandemic has led to widespread staffing shortages, and turnover including in ambulatory surgery centers, which has and may continue to impact elective procedures.

Additionally, some of our vendors are continuing to experience supply challenges, both in the acquisition of raw materials as well as due to labor shortages and disruption. As a result of these supply chain challenges and due to current inflationary pressures, we have experienced higher costs for certain components and raw materials. We expect these supply challenges to continue into 2023. These challenges have occasionally led to longer lead times for, and delays and partial or unfulfilled deliveries of certain components needed for the manufacture of our products, in some cases requiring us to find alternative sources for materials. If these delays and partial or unfulfilled deliveries persist, they could impact our ability to ship some of our products to our customers, or bring some of our pipeline products to market, in a timely manner. For additional information, see the section titled Risks Related to Our Business within Item 1A. Risk Factors of this Annual Report on Form 10-K.

## **Recent Developments**

### ***2023 U.S. reimbursement rates***

On November 1, 2022, the United States (U.S.) Centers for Medicare & Medicaid Services (CMS) published its final rules for 2023 Medicare physician fee payment rates and 2023 Medicare facility fee payment rates for services furnished in both the ambulatory surgery center and hospital outpatient settings (Final Rules). These Final Rules did not materially modify the 2022 payment rates, which had reflected a significantly lower physician fee, a slightly lower facility fee reimbursement to ambulatory surgery centers, and a higher facility fee reimbursement to hospitals, related to the implantation of trabecular bypass stents, such as our *iStent* family of products, in conjunction with cataract surgery, compared to the 2021 payment rates. We estimate that approximately 80% of procedures utilizing our 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. Additionally, the Final Rules set facility fee payment rates for standalone insertion of an aqueous drainage device in the ambulatory surgery center and hospital settings, the procedure that such facilities would use with our *iStent infinite* product, that were substantially unchanged from the 2022 payment rates, which were lower than anticipated. These CMS reimbursement rates contained in the Final Rules took effect January 1, 2023. The physician fee payment rate for this procedure will be set by the multi-state, regional contractors, or Medicare Administrative Contractors (MACs), responsible for administering Medicare claims, the vast majority of which have not yet done so, and therefore will vary from region to region and is unknown at this time.

U.S. Glaucoma volumes were negatively impacted during our third and fourth quarter of 2021 as typical customer ordering patterns were disrupted and trialing of competitive products increased in anticipation of the potential 2022 CMS physician and facility fee reimbursement rate decreases becoming effective. The 2022 significantly lower physician fee reimbursement rate had an adverse impact on 2022 procedural *iStent* family product volumes, in conjunction with cataract surgery, which consequently impacted our 2022 U.S. combo-cataract Glaucoma revenues, gross profit, and net income, and we anticipate that such adverse impact will continue into 2023, the full extent of which is not known at this time.

## **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 principal end markets within ophthalmology: glaucoma, corneal disorders and retinal diseases.

### ***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 four primary commercialized products designed to treat glaucoma: the *iStent*, the *iStent inject*, the *iStent inject W*, and the *iStent infinite*.

The *iStent*, the *iStent inject* (first generation), and the *iStent inject W* (second generation) are micro-bypass stents, approved by the U.S. Food and Drug Administration (FDA)-approved that improve aqueous humor outflow and are inserted through the small corneal incision made during cataract surgery, and 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 FDA clearance in 2012 and was the first commercially available MIGS treatment solution. The *iStent inject* and *iStent inject W* devices include two stents pre-loaded in an auto-injection system designed to allow the surgeon to inject stents through a single corneal entry. The *iStent*, *iStent inject*, and *iStent inject W* procedures are currently reimbursed in the U.S. by Medicare and all major national private payors. The *iStent* technologies are commercially available in numerous countries, including Australia, Brazil, Canada, Japan, the United Kingdom, and a majority of the European Union (EU) members, and other countries, even though reimbursement may not always be available for all such procedures. The second generation *iStent inject W* has replaced the first generation *iStent inject* in nearly every country in which we sell them, and now comprises the vast majority of sales globally in the *iStent inject* line of products.

In August 2022, we received 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* includes three heparin-coated 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 indicated for use in a standalone procedure for glaucoma patients.

We are also developing several pipeline products for the treatment of glaucoma patients, including *iDose TR*, which has not yet been approved for commercialization. The *iDose* drug delivery system is a targeted injectable implant based on our micro-scale device-platform that is designed to continuously deliver therapeutic levels of medication from within the eye for extended periods of time. We completed patient enrollment and randomization in our Phase 3 clinical trials in 2021 for *iDose TR*. In September 2022, we announced topline data for both Phase 3 pivotal trials of *iDose TR* that achieved its pre-specified primary efficacy endpoints through 3 months and demonstrated tolerability and a favorable safety profile through 12 months. Based on the combined efficacy and safety results from both Phase 3 pivotal trials, we anticipate submitting a new drug application (NDA) for *iDose TR* in 2023 with potential FDA approval of this product by the end of 2023.

Additionally, our glaucoma pipeline includes the next-generation extended release *iDose TREX*; *iDose ROCK*; and programs for our *iLution* platform, including *iLution Travoprost*; which are still in a research and development (R&D) stage.

In addition to our organic R&D efforts, we have licensed from 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 are evaluating alternate regulatory pathways for approval. As such the timing of a potential approval and U.S. commercial launch is currently unknown. We have commercialized the PreserFlo MicroShunt in Australia and Canada beginning in 2021.

### **Corneal Disorders**

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, 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 *Photrex* 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 the removal of the epithelium (often referred to as "*iLink* epi-on"). As a result of this Phase 3 trial, we began to prepare for an NDA submission. However, in 2022, based on feedback from the FDA during our pre-NDA submission meeting, we made the decision to commence a second confirmatory Phase 3 clinical trial for *iLink* epi-on to support future NDA submission. We commenced patient enrollment for this trial in the first quarter of 2023. We also expect to advance a third generation *iLink* therapeutic system into clinical trials during 2023. Internationally, our pharmaceutical therapies can also be administered with the KXL System to address corneal weakening caused by refractive surgery such as LASIK. 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* 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 eye disorders. Several *iLution* platform products leverage an exclusive global licensing arrangement with Intratus 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 (GLK-301) and presbyopia (GLK-302). In January 2023, we announced promising initial Phase 2a results for GLK-301. Based on these encouraging Phase 2a observations, we plan to advance GLK-301 into a Phase 2b clinical trial in 2023.

Lastly, in September 2021, we entered into a licensing agreement with Attillaps Holdings, Inc. (Attillaps) to research, develop, manufacture and commercialize Attillaps' proprietary library of investigational pharmaceutical compounds that target the eradication of Demodex mites, which are the root cause of Demodex blepharitis and often associated with meibomian gland dysfunction and related ophthalmic diseases.

### ***Retinal Diseases***

Retinal diseases vary widely but universally affect the retina, a thin layer of tissue inside the back wall of the eye containing light-sensitive cells that convert light into neural signals. Most retinal diseases cause visual impairment, including blurred or distorted vision and vision loss. Our R&D efforts in our retinal franchise are focused on treating AMD, DME, RVO, and other retinal diseases. AMD is a progressive disease that occurs when the macula, the central portion of the retina, is impaired, which can result in severe vision problems. DME is highly prevalent among individuals with type 2 diabetes and is associated with diabetic retinopathy (DR), the impairment of small blood vessels in the retina caused by increased glucose levels. Advanced DR can lead to fluid leaking into the macula, which causes DME and severe vision impairment. RVO occurs when the flow of blood from the retina is blocked, often due to a blood clot blocking the retinal vein, which can result in severe vision problems.



We are developing sustained release (SR) pharmaceutical retinal platforms leveraging our expanded pharmaceutical and sustained drug delivery R&D capabilities, including Triamcinolone Acetonide SR, Multi-Kinase Inhibitor SR and Anti-VEGF SR. If commercialized, these platforms would be designed to treat AMD, DME, 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 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 MIGS technologies through our *iDose* and *iStent* platforms;
- to further enhance treatment options for keratoconus, while expanding *iLink* and CXL indications to include treatment for certain refractive and other corneal conditions;
- to develop dropless, transdermal pharmaceutical therapies for dry eye disease, presbyopia, glaucoma and other 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 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, 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 through direct sales organizations in seventeen countries and a network of distribution partners in other markets where we do not have a direct commercial presence or maintain a modest commercial presence. In 2022, sales to customers inside U.S. and internationally accounted for 72% and 28% of our net sales, respectively. No single customer or distributor accounted for more than 10% of our total net sales in 2022. For the year ended December 31, 2022, our *iStent* technologies, the *iStent*, the *iStent inject*, and the *iStent inject W* and related accessories, which comprise our key *iStent* platform, accounted for approximately 76% of our net sales, while our *iLink* therapies accounted for approximately 24% 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 change characterize the areas in which we compete. Our present or future products could be rendered obsolete as a result of advances by one or more of our present or future competitors or by other surgical or pharmaceutical therapy development. 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 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 Ivantis, Inc. (which was acquired by Alcon in January 2022), Sight Sciences and New World Medical. However, there are a considerable number of large and small companies providing more invasive surgical glaucoma technologies, 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 have, under an orphan drug designation, the only FDA approved bio-activated pharmaceutical therapy for the treatment of keratoconus but globally we compete against numerous providers of corneal crosslinking therapies such as PeschkeTrade GmbH. Our corneal disorder pipeline, if approved, would vastly expand our competition to numerous large companies such as AbbVie Inc., Alcon 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 pipeline, if approved, may face substantial competition from large pharmaceutical companies such as AbbVie Inc., Novartis AG, Genentech/Roche, Regeneron and Bayer, and there are also a considerable number of large and small companies with development efforts in the field.

### **Facilities, Manufacturing and Distribution**

Our manufacturing operations for the *iStent* family of products are located in an approximately 98,000 square foot campus in San Clemente, California which is comprised of two main buildings. 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 the second quarter of 2022, we relocated our corporate headquarters, 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 for the *iStent* family of products 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.

### **Intellectual Property**

The 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 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, 2022, we owned or exclusively licensed in certain fields of use over 300 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., Attillaps Holdings, Inc. and Iveena Delivery Systems, 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 2023 and 2038.

## Government Regulation

Our 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, which has resulted in, and will likely continue to result in, increased prices to bring new products to market.

### *U.S. Regulation & 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 Requirements*

Each 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* 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*, *iStent inject W* and the PreserFlo MicroShunt are categorized as Class III devices and thus would generally be 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 would be sufficient.

#### *PMA Approval Pathway*

In 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 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 in material adverse enforcement action, including withdrawal of the 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 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 investigational drug exemption (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 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 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;
- 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;
- 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 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, 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-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 the following sanctions:

- warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- recalls, withdrawals, or administrative detention or seizure of products;
- operating restrictions or partial 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 extensive regulatory approval process implemented by the FDA under the FDCA. Several of our pipeline products, including our *iDose* implants and our *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 IND 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 and is tested 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 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 recently 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 combination products. This may impact some of our pipeline products, such as our *iDose* drug-eluting implants. These products that are considered to be drug-device combination products will require review and coordination by 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 each of these areas, as above, the FDA and other regulatory authorities have broad regulatory 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;
- the federal civil False Claims Act 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 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. 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 pricing metrics to government programs, such as average sales price, 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; penalties may apply in some cases when such metrics are not submitted accurately and timely.

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.

Additionally, some states have proposed or enacted legislation that will create new data privacy and security 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. Violations of these laws, or 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.

### *Reimbursement*

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., physicians are typically paid separately from the facility for surgical procedures involving our products. 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. Effective beginning in 2022, the temporary Category III CPT codes associated with payment rates for procedures related to our *iStent*, *iStent inject* and *iStent inject W* products 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. We estimate that approximately 80% of procedures utilizing our 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. Even though a permanent billing code has been assigned to a product, there is no guarantee that coverage will be provided.

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. Prior to expiration of a temporary code, there are two options: submit an application to convert a temporary code to a permanent code or submit an application for a five-year extension of the temporary code. In connection with a transition to a permanent code, both the physician fee and facility fee associated with the procedures using our *iStent infinite* product 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.

Our *Photrex* pharmaceutical therapy has received a permanent healthcare common procedure coding system J code and we have obtained temporary Category III CPT code for the professional fees associated with CXL.

In the U.S., no uniform policy of coverage and reimbursement exists among third-party 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.

### ***International Regulation & Reimbursement***

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 FDA approval. 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., other 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 with a transition period through May 2024 at the latest (although an extension of this date has been proposed by the European Commission), and will bring 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.

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, or GDPR, became effective in May 2018 and applies across the EU (with the exception of the United Kingdom, which has adopted the UK Data Protection Act 2018 and 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 to comply with 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 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.

#### *Other*

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 Health & Safety Administration, 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.

## Human Capital 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, 2022, we had 783 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, talent development, employee retention, material aspects of employee compensation as well as diversity and inclusion 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 38% female employees and 42% racially or ethnically diverse employees as of December 31, 2022. During 2022, of the promotions that were earned within our workforce, 41% were earned by female employees and 53% 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, in 2021 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 2022, we offered a wellness credit to all U.S. employees that provides reimbursement for certain health-related expenses such as gym memberships, to incent a healthy lifestyle. 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.
- **Philanthropy and Volunteerism:** We created the Glaukos Charitable Foundation to assist the company in its philanthropic endeavors. In 2022, Glaukos donated approximately \$9.6 million worth of its products to assist individuals in need. We regularly hold local volunteer events and fundraising campaigns, including approximately 25 in 2022, 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 175 disadvantaged families globally

to help provide a more special holiday experience. 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. 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 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. 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 flu and COVID vaccine events, health surveys, apps and other resources to encourage and support our employees in achieving their best health.
- 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).

## Available Information

Our 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](http://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](http://www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including us.

## **Item 1A. Risk Factors**

*The risks 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 under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”*

### **Risks Related to Our Business**

***The reduced reimbursement rates established by CMS for 2022 and 2023 have impacted, and may continue to materially and adversely impact, our business operations and financial results.***

As described in Item 1, Business, “Recent Developments –2023 U.S. Reimbursement rates” contained in this Annual Report on Form 10-K, the U.S. Centers for Medicare & Medicaid Services’ (CMS’) 2022 Medicare physician fee payment rates and 2022 Medicare facility fee payment rates imposed a new, significantly lower physician fee and a slightly reduced facility fee 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 setting. We believe these CMS physician fee and facility fee rate decreases disrupted traditional customer ordering patterns and resulted in our customers’ trialing of competitive products, causing reduced glaucoma sales volumes in the U.S. in 2022. These rates were not significantly modified in CMS’ final rules for 2023 physician fee and facility rates. We expect the reduction of the physician fee will continue to have an adverse impact on procedural *iStent* family product volumes, in conjunction with cataract surgery, in 2023 as well as on our U.S. combo-cataract glaucoma revenues, gross profit, and net income, the full extent of which is not known at this time.

Additionally, the facility fee payment rates for the standalone procedure that hospitals and ambulatory surgery centers will use with Glaukos’ *iStent infinite* product, which received 510(k) clearance from the U.S. Food and Drug Administration (FDA) on August 2, 2022, were lower than anticipated for 2022. These rates were not significantly modified by CMS for 2023 facility fee payment rates. The physician fee payment rate for this procedure will be set by the multi-state, regional contractors, or Medicare Administrative Contractors (MACs), responsible for administering Medicare claims, the vast majority of which have not yet done so, and therefore will vary from region to region and is unknown at this time. This physician fee payment rate, alone or in combination with the standalone facility fee payment rate, may result in inadequate reimbursement and impact the use of this product, and our net sales.

***Unfavorable global and regional conditions have adversely affected, and could continue to materially and adversely affect, our business, results of operations, financial condition, liquidity, and cash flows.***

Unfavorable global and regional conditions, including inflation, volatility in the financial and credit markets, higher interest rates and capital costs, geopolitical conflicts, changes in supply and demand resulting in shortages and delays, labor shortages and turnover, natural disasters, energy costs, currency fluctuations, governmental actions such as mandatory lockdowns, and other conditions beyond our control, 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 cash flows. The weak or declining economy has also, and likely will continue to, strain our third-party manufacturers or suppliers, both in raw material acquisition and due to labor shortages, resulting in supply disruptions, that could impact our ability to ship some of our products to our customers or bring some of our pipeline products to market in a timely manner, which could harm our reputation and affect our product sales, or may cause our customers to delay making payments. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the economic climate and financial market conditions could adversely affect our business, financial condition or results of operations.

***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 those related 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, material financial or operational impacts as a result of COVID-19 or other public health crises, including:

- Impacts or delays to our product development efforts 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;
- Widespread staffing shortages and turnover, including in ambulatory surgery centers, and mandatory and voluntary quarantining, which may impact elective procedures;
- 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;
- Patient reluctance to seek primary care from optometrists and ophthalmologists or undergo medical procedures during or following outbreaks of disease;
- 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 2022 and anticipate will continue into the near future;
- Restrictions on the ability of our personnel to access customers and clinical sites for training and support;
- Challenges to our capacity to manufacture, sell and support the use of our products; and
- Volatility in credit or financial markets.

For example, restrictions on elective procedures and therapies and the closures of ophthalmic practices during the COVID-19 pandemic impacted the progress of our pipeline products, such as the slowdown in new patient enrollment in our *iDose* clinical trial in 2020 and 2021, which delayed the *iDose* approval timeline. Future public health crises could have a similar adverse impact. While we cannot predict the full impact of COVID-19 or future pandemic, epidemic or infectious disease outbreaks on the timing of completion of our clinical trials and the expected regulatory approvals of our pipeline products, our disclosed targeted approval dates anticipate, to our best estimate, such impact.

***If the supply and/or manufacture of our principal revenue-producing products, the iStent, the iStent inject models and our Photrexa therapies, is materially disrupted, it may adversely affect our ability to manufacture products and could reduce our gross margins and negatively affect our operating results.***

Our sole manufacturing location for our *iStent* products is an approximately 98,000 square foot campus located in San Clemente, California, where we manufacture, inspect, package, release and ship nearly all of our *iStent* platform products. In 2022, we relocated our corporate administrative headquarters to a new facility in Aliso Viejo, California (Aliso Facility), which is the location where we conduct substantially all of our R&D activities, customer and technical support, and management and administrative functions. If either of our San Clemente or Aliso Facility suffers a crippling event or a natural disaster such as an earthquake, fire or flood, 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* 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 regulations, we may be unable to obtain components if our component suppliers are found to be in violation of such standards and we may have difficulty quickly engaging additional or replacement suppliers for some of our critical components, 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. Even if we are able to identify and qualify a suitable second source to replace one of our key suppliers, if necessary, that replacement supplier would not have access to our previous supplier's proprietary

processes and would therefore be required to develop its own, which could result in significant delay. 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 *Photrex*a therapies are produced by a small number of contract manufacturing organizations. The systems that bio-activate our *Photrex*a 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. As of December 31, 2022, we had an accumulated deficit of approximately \$464.4 million, principally costs incurred in our clinical trial, research and development (R&D) programs, our selling, general and administrative expenses, and from amortization expense related to our 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 public offering, the issuance of notes payable, cash exercises of stock options and warrants to purchase equity securities, cash generated from commercial operations and the issuance of the Company's 2.75% convertible notes due 2027 (Convertible Notes). To implement our global business strategies we need to, among other things, fund ongoing R&D activities, expand our manufacturing capabilities, grow our sales and marketing organization, enforce or defend our intellectual property rights, acquire companies or in-license products or intellectual property, and obtain regulatory clearance or approval to commercialize our existing products in international markets or to commercialize those currently under development in the U.S. and internationally. As a result, we expect our expenses to 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, 2022 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, impacts from the COVID-19 or other pandemic, macroeconomic conditions, fluctuating demand, pricing pressures applicable to our products, changes in foreign currency exchange rates, Medicare payment rates established by CMS, commercialization of our new and existing products and the marketing of competitive products, results of clinical research and trials, regulatory approval requirements and timings and 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 of raw materials, timing or volume of customer orders and the length of our sales cycle, 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*, which we began selling in the U.S. in 2012, the *iStent inject*, which we began selling in the U.S. in the second half of 2018, and its successor, the *iStent inject W*, launched in the second half of 2020, as well as our *Photrex*a therapies, which we acquired in connection with our acquisition of Avedro, Inc. (Avedro) in November 2019. We expect to continue to derive a significant portion of our net sales from the *iStent*, the *iStent inject* models and the *Photrex*a therapies.

It is important that we continue to build a more complete product offering. Developing additional products is

expensive and time-consuming. Even if we are successful in developing our additional pipeline products, the success of our new product offerings is inherently uncertain and there can be no assurance that our products will receive regulatory approval or 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 by our competitors of products embodying superior technologies, features or better product safety, quality or efficacy. 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, our research programs, which are expensive and time-intensive, 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.

***As 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 in seventeen countries 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 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, and 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
- the imposition of costly and complex export licensing requirements and restrictions, particularly relating to technology.

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 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.

***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 components included in our products. Because our products are highly complex, the occurrence of performance issues may increase as we continue to introduce new products and rapidly scale up manufacturing to meet 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, 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 or lost revenue 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, which 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. 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 product demand which could strain our manufacturing capacity; 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, key employees and 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 or good reason, could prevent or delay our growth plans and the implementation and completion of our strategic objectives, or divert management's attention to seeking qualified replacements. Our U.S. 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 and iVeena pharmaceutical compounds. 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 the 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 technology infrastructure against cyber incidents, network security breaches, 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 technology systems, including telecommunications, the internet, network communications, email and various computer hardware and software applications. We rely on our information technology 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 technology 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 cyber-based incidents, some of which we have experienced and which we continue to monitor. Cyber 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. While none of the cyber incidents or service interruptions that we have experienced to date have had a material adverse impact on our business, financial condition or operations, we cannot assure that future incidents will not materially and adversely impact us. In addition, some of our software systems are cloud-based data management applications, 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 information, all of which could have a material adverse effect on our reputation, business, financial condition and operating results.

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 cyber 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 business, 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. 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 under applicable 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, 2022, we had approximately \$449.1 million, \$321.1 million and \$10.8 million of net operating loss (NOL) carryforwards for federal, state and foreign purposes, respectively. Federal NOL carryforwards incurred prior to 2018 begin to expire in 2024, while federal NOL carryforwards of \$241.1 million will not expire but can only be used to offset 80 percent of future taxable income. State and foreign NOL carryforwards begin to expire in 2023. At December 31, 2022, we had federal and state R&D credit carryforwards of approximately \$40.4 million and \$22.3 million, respectively. Federal and \$4.3 million of state credits begin to expire in 2023, while \$18.0 million of state credits carry forward indefinitely. 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 under the Internal Revenue Code of 1986 (IRC) Section 382 and Section 383 if the Company experiences 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 period to utilize the remaining tax attributes before they expire.

## **Risks Related to Indebtedness**

***The requirement that we service our 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, 2022, we had \$287.5 million in principal amount of indebtedness as a result of the issuance of the Convertible Notes. We may also 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; 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.

***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 Convertible 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 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, 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.

***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 cover, subject to customary adjustments, the number of shares of common stock initially underlying the Convertible Notes. The capped call transactions are 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 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 activity could impact the market price of our common stock.

The option counterparties to the capped call transactions are financial 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 an 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**

***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, 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” contained in this Annual Report on Form 10-K for additional information. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, 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 approval for additional indications or that our future products will

receive clearance or approval on a timely basis, if at all. Additionally, based upon a recent FDA determination, our pipeline products that are determined to be drug-device combination products will require review and coordination by each of FDA's drug and device centers prior to approval, which may delay approval. 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 recent 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 clinical 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 responsible for 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 clinical 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.

As part of the regulatory application and approval process, the FDA will generally conduct a pre-approval inspection of the applicant or its third-party manufacturers' or suppliers' manufacturing facilities to ensure compliance with the FDA's Quality System Regulation (QSR) for medical devices or current Good Manufacturing Practice (cGMP) regulations for drug products. 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.

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 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 regulations, combination products are subject to the quality system and good manufacturing requirements applicable to both drugs and medical devices. 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 withdrawal. Any recall or product withdrawal, whether required by the FDA or another regulatory authority or initiated by us, could harm our reputation with customers and negatively affect our sales.

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 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 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 exposure to international markets increases 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 foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare systems in ways that could impact our ability to sell our products profitably, if at all. In the U.S. in recent years, new legislation has been proposed and adopted at the federal and state levels that is effecting major changes in the healthcare system. 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 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 May 2017, the EU adopted Medical Devices Regulation 2017/745 (MDR), which repealed and replaced the Medical Device Directive (MDD). MDR went into effect in May 2021, and provides for stricter controls of medical devices than did MDD. Under provisions that govern the transition from MDD to MDR, medical devices with notified body certificates issued under the MDD prior to May 2021 may continue to be marketed and sold as long as those certificates are valid (up to a maximum of five years from the date of issue) or until May 2024 at the latest, although legislation was proposed by the European Commission in January 2023 to extend that date for qualifying products. 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. 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, 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. Additionally, the U.K.'s withdrawal from the EU and the end of the mutual recognition and related trade facilitating effects for medical devices between the EU and Switzerland in May 2021 have added certain costs and complexities to the shipment and sales of our products in those countries.

We may from time to time increase the prices of our products, as we do 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.

Additionally, on August 16, 2022, the U.S. government enacted the Inflation Reduction Act of 2022, which is designed to, among other things, have a direct impact on drug prices and reduce drug spending by the federal government. The Inflation Reduction Act 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. The Inflation Reduction Act of 2022 or other similar legislation could have the effect of reducing the prices we can charge and reimbursement we receive for our products, thereby reducing our revenues and profitability.

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, our business would be harmed. In addition, any change in the laws or regulations that govern the clearance and approval processes 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.

***Inadequate or inconsistent reimbursement for our products may adversely impact our business.***

Our ability to successfully commercialize and achieve market acceptance of our products, as well as 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 Annual Report on Form 10-K 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 our new products like *iAccess*, a precision blade, and *iPRIME*, a viscoelastic delivery system, as well as sporadic volatility in reimbursement levels of existing products, including our *Photrex* therapy. 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. MACs have in the past, and may in the future, change coverage terms, which could result in inadequate reimbursement and impact the use of our products. 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 earlier in these Risk Factors under the heading “Risks Related to Our Business.” 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 other products in development, we may be subject to significant pricing pressure, which could harm our business, results of operations, financial condition and prospects. In the foreign markets in which we operate, different pricing and reimbursement systems, which could result in lower reimbursement, could harm our ability to operate our business.

We cannot predict to what extent current global economic conditions, including the continuing effects of the COVID-19 or a future pandemic, may disrupt global 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 payor coverage to government payor coverage, or an increase in demand for patient assistance and/or free drug programs, any of which could adversely affect our net revenue. In addition, payers consistently engage in cost containment efforts, which could include efforts to decrease 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 of a third party, including those rights owned by our competitors. Additionally, third parties could assert 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 Company, (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Company or its stockholders, (iii) any action or proceeding asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our Charter or Bylaws, or (iv) any action or proceeding asserting a claim governed by the internal affairs doctrine (the Delaware Exclusive Forum Provision). The Delaware Exclusive Forum Provision is intended to apply to claims arising under Delaware state law and would not apply to claims brought pursuant to the Exchange Act or the Securities Act, or any other claim for which the federal courts have exclusive jurisdiction.

Further, our Bylaws provide that the federal district courts of the U.S. will, to the fullest extent permitted by law, be the exclusive forum for resolving any complaint asserting a cause of action under the Securities Act (the Federal Forum Provision). Our decision to adopt the Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law and means that suits brought by stockholders to enforce any duty or liability created under the Securities Act must be brought in federal court and cannot be brought in state court.

The exclusive forum provisions in our Charter and Bylaws will not relieve us of our duties to comply with the federal securities laws and the rules and regulations thereunder and, accordingly, actions by our stockholders to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder must be brought in federal courts. Our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations. The exclusive forum provisions in our Charter and Bylaws may limit a stockholder's ability to bring a claim in a judicial forum of its choosing for disputes with the Company or its directors, officers or other employees, which may discourage such lawsuits. In addition, stockholders who do bring a claim in the Court of Chancery of the State of Delaware pursuant to the Delaware Exclusive Forum Provision could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near Delaware. The court in the designated forum under our exclusive forum provisions may also reach different judgments or results than would other courts, including courts where a stockholder would otherwise choose to bring the action, and such judgments or results may be more favorable to the Company than to our stockholders. Further, the enforceability of similar exclusive forum provisions in other companies' organizational documents has been challenged in legal proceedings, and it is possible that a court could find any of our exclusive forum provisions to be inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings. If a court were to find all or any part of our exclusive forum provisions to be inapplicable or unenforceable in an action, we might incur additional costs associated with resolving such action in other jurisdictions.

## **ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

## **ITEM 2. PROPERTIES**

The Company leases two adjacent facilities located in San Clemente, California. Each of these leases expires on May 31, 2030, and each contains an option to extend the lease for one additional five year period at market rates. The total leased square footage of both facilities equals approximately 98,000. Additionally, the Company leases one property containing three office buildings, comprising approximately 160,000 rentable square feet of space, located in Aliso Viejo, California. The term of the Aliso Facility commenced on May 1, 2019 and continues for thirteen years. The agreement contains an option to extend the lease for two additional five year periods at market rates. On December 18, 2018, we also purchased approximately 2.5 acres of vacant land located adjacent to the Aliso Facility for future expansion purposes. In 2022, the Company relocated its corporate administrative headquarters, along with certain laboratory, R&D and warehouse space, to the Aliso Facility. The Company's San Clemente locations will continue to serve as its main manufacturing location for the foreseeable future.

Additionally, we currently occupy approximately 60,000 square feet of leased manufacturing space in Burlington, Massachusetts pursuant to a lease agreement that expires on July 31, 2033. Our additional U.S.-based and foreign subsidiaries' leased office space, which includes small administrative offices in Australia, Brazil, Canada, Germany, Japan and the United Kingdom, totals less than 14,000 square feet.

We believe our existing properties are well maintained, in good operating condition and are adequate to support our present level of operations.

## **ITEM 3. LEGAL PROCEEDINGS**

Neither we nor any of our subsidiaries is a party to, and none of their respective property is the subject of, any material legal proceeding, although we are from time to time party to legal proceedings that arise in the ordinary course of business.

## **ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

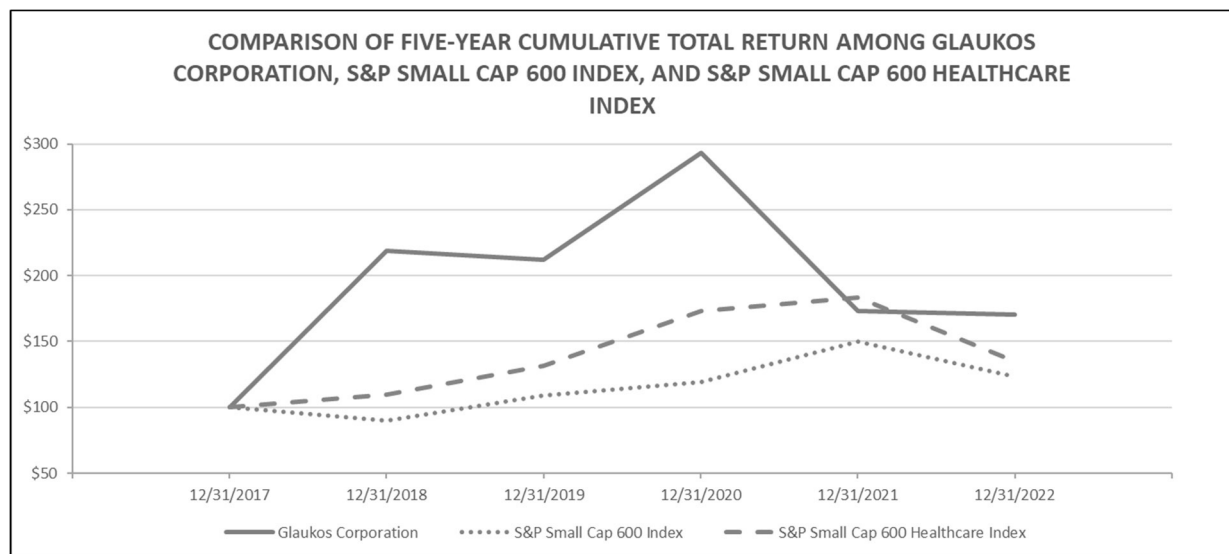
#### Market Information for Common Stock

Our common stock trades on the New York Stock Exchange (NYSE) under the symbol "GKOS".

As of February 22, 2023, we had 53 holders of record of our common stock. The actual number of stockholders is greater than this number of record holders, and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. The number of record holders also does not include stockholders whose shares may be held in trust by other entities.

#### Stock Performance Graph

The following performance graph shows the cumulative total stockholder return during the last five years in (i) our common stock, (ii) the S&P Small Cap 600 index and (iii) the S&P Small Cap 600 Healthcare index. The graph assumes that \$100 was invested at the closing price of our common stock on the last trading day of fiscal year 2017 and all dividends were reinvested. Stockholder returns over the indicated period should not be considered indicative of future stockholder returns.



	12/31/2017	12/31/2018	12/31/2019	12/31/2020	12/31/2021	12/31/2022
Glaukos Corporation	\$ 100.00	\$ 218.99	\$ 212.36	\$ 293.41	\$ 173.26	\$ 170.29
S&P Small Cap 600 index	\$ 100.00	\$ 90.25	\$ 109.07	\$ 119.51	\$ 149.71	\$ 123.63
S&P Small Cap 600 Healthcare index	\$ 100.00	\$ 109.77	\$ 131.87	\$ 173.30	\$ 183.28	\$ 134.84

*This performance graph shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities under that section and shall not be deemed to be incorporated by reference into any of our filings under the Securities Act or the Exchange Act.*

**Dividend Policy**

We have never declared or paid any cash dividends on our common stock or any other securities. We anticipate that we will retain all available funds and any future earnings, if any, for use in the operation of our business and do not anticipate paying cash dividends in the foreseeable future.

**ITEM 6. [RESERVED]**

## **ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*You should read the following discussion and analysis of our financial condition and results of operations together with our audited consolidated financial statements and related notes included in this Annual Report on Form 10-K. This discussion and analysis and other parts of this Annual Report on Form 10-K contain forward-looking statements that reflect our current plans, expectations, estimates and beliefs that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results and the timing of selected events may differ materially from those discussed in these forward-looking statements. You should carefully read Item 1A - "Risk Factors" included in this Annual Report on Form 10-K to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Special Note Regarding Forward-Looking Statements and Industry Data."*

### **Overview**

We are an ophthalmic medical technology and pharmaceutical company focused on developing novel therapies 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, and continue to develop a portfolio of technologically distinct and leverageable platforms to support ongoing pharmaceutical and medical device innovations. Products or product candidates for 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, diabetic macular edema, and retinal vein occlusion.

### **Impact of the Current Global Economic Environment**

Global and regional economies, the markets we serve and financial markets have recently experienced significant volatility including inflation, supply shortages or delays, geopolitical developments, changes in supply and demand, labor shortages and turnover, natural disasters, higher energy costs, health epidemics or pandemics (including the COVID-19 pandemic), currency fluctuations, governmental actions such as mandatory shutdowns, and other conditions which have led to disruptions in commerce and pricing stability. The duration and scope of these conditions cannot be predicted, and therefore, it is uncertain what long-term impacts these economic pressures may have on our business.

While the COVID-19 pandemic materially impacted the global demand for our products, we have seen a general return toward more normalized levels for cataract and keratoconus procedures, with periodic volatility in certain geographies in which we operate, through December 31, 2022. Nevertheless, our business may be impacted by future developments, including any subsequent outbreaks or new variants of the COVID-19 virus, or other future health crises, which may require re-closures or other preventative measures. Additionally, the COVID-19 pandemic has led to widespread staffing shortages, including in ambulatory surgery centers, which has and may continue to impact elective procedures.

Additionally, some of our vendors are continuing to experience supply challenges, both in the acquisition of raw materials as well as due to labor shortages and disruption. As a result of these supply chain challenges and due to current inflationary pressures, we have experienced higher costs for certain components and raw materials. We expect these supply challenges may continue into 2023. These challenges have occasionally led to longer lead times for, and delays and partial or unfulfilled deliveries of certain components needed for the manufacture of our products, in some cases requiring us to find alternative sources for materials. If these delays and partial or unfulfilled deliveries persist, they could impact our ability to ship some of our products to our customers, or bring some of our pipeline products to market, in a timely manner.

## Financial Overview

The most important financial indicators that we use to assess our business are net sales, gross margin, operating expenses, and cash on hand.

	December 31, 2022	December 31, 2021
Net sales	\$ 282,862	\$ 294,011
Gross margin	76 %	77 %
Operating expenses	\$ 296,196	\$ 260,256
Cash, cash equivalents, short-term investments and restricted cash	\$ 359,773	\$ 423,467

Please see *Results of Operations* and *Liquidity and Capital Resources* below for a detailed discussion of each of the above items including analysis of the fluctuations from year to year.

We incurred net losses of \$99.2 million, \$49.6 million and \$120.3 million for the years ended December 31, 2022 and December 31, 2021, and December 31, 2020, respectively and as of December 31, 2022, we had an accumulated deficit of \$464.4 million.

## Recent Developments

### ***2023 U.S. reimbursement rates***

On November 1, 2022, the U.S. Centers for Medicare & Medicaid Services (CMS) published its final rules on 2023 Medicare physician fee and facility fee payment rates (2023 Final Rules) for procedures using our *iStent* family of products furnished in both the ambulatory surgery center and hospital outpatient settings in conjunction with cataract surgery, as well as the facility fee payment rates, in both hospital and ambulatory surgery center settings, and for standalone insertion of an aqueous drainage device, such as our *iStent infinite* product. The 2023 Final Rules do not materially modify the Final Rules (as defined below) established for 2022.

### ***iStent infinite***

On August 2, 2022, we received 510(k) clearance from the U.S. Food & Drug Administration (FDA) to market the *iStent infinite*, an implantable device intended to reduce the intraocular pressure of the eye. It is indicated for use in adult patients with primary open-angle glaucoma in whom previous medical and surgical treatment has failed. We began commercial launch activities for this product in the fourth quarter of 2022.

### ***iLink Epioxa***

In November 2022, we made the determination, based upon recommendations from the FDA in recent pre-New Drug Application (NDA) meetings, that we will not submit an NDA for our *Epioxa (Epi-On)* bio-activated pharmaceutical therapy for the treatment of keratoconus this year, but will instead conduct a second pivotal confirmatory study for this product to support a future NDA submission. We currently estimate that enrollment in this study will commence in the first half of 2023.

### ***iVeena Exclusive License Agreement***

Effective June 9, 2022, we entered into an Exclusive License Agreement (iVeena License Agreement) with iVeena Delivery Systems, Inc. (iVeena), pursuant to which iVeena granted us an exclusive, worldwide license to manufacture and sell products incorporating certain of iVeena's owned or controlled technologies, including certain chemical compositions, that may be utilized for the treatment of keratoconus. Pursuant to the terms of the iVeena License Agreement, we made a one-time upfront payment to iVeena of \$10.0 million. 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 and royalty payment obligations depending on the success of the development, approval and commercialization of the proprietary technologies.

## Factors Affecting Our Performance

The CMS final rules for 2022 Medicare physician fee payment rates and 2022 Medicare facility fee payment rates for services furnished in both the ambulatory surgery center and hospital outpatient settings (Final Rules) took effect on January 1, 2022. Compared to the reimbursement rates in effect for 2021, the Final Rules contained a significantly lower physician fee related to the implantation of trabecular bypass stents, such as our *iStent* family of products, in conjunction with cataract surgery. Conversely, the facility fee schedule related to surgeries that include implantation of trabecular bypass stents, such as our *iStent* family of products, in conjunction with cataract surgery, slightly decreased reimbursements to an ambulatory surgery center and increased reimbursements to a hospital. Additionally, the Final Rules established facility fee payment rates that were lower than anticipated for standalone insertion of an aqueous drainage device in the ambulatory surgery center and hospital settings, which would be the procedure that such facilities would use with our *iStent infinite* product. We estimate that approximately 80% of procedures utilizing our 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. The significant reduction of the physician fee had a negative impact on 2022 U.S. procedural volumes of our *iStent* family of products, in conjunction with cataract surgery, which we expect will continue for 2023, adversely affecting our U.S. combo-cataract Glaucoma revenues, gross profit, and net loss, the full extent of which is not known at this time.

We expect our results of operations for 2023 and our near-term performance to reflect increasing competitive dynamics, the impact of the reduced physician fee reimbursement rates contained in the 2023 Final Rules, the continuing disruption resulting from labor and supply shortages and the effects of the macroeconomic environment, the full effects of which are difficult to predict at this time. In addition to the foregoing factors, our operations to date have been, and we believe our future growth and success will be, impacted by the following:

- the rate at which we expand our global sales and marketing infrastructure, and the speed at which we can continue increasing access to and awareness of our products to patients and physicians;
- our ability to timely satisfy the requirements set by regulatory authorities for approval of new products and approved indications for use;
- future coverage and reimbursement rates set by CMS, third-party commercial payors and foreign regulatory authorities for the procedures using our products, and our competitors' products, as well as uncertainty associated therewith;
- the extent to which our customers trial competitive products;
- our ability to maintain a competitive position in the development of new products for the treatment of chronic eye diseases, given that our industry is highly competitive and subject to rapid and profound technological, market and product-related changes;
- the impact of publications of clinical results by us, our competitors and other third parties on 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;
- the physicians who use our products may not perform procedures during certain times of the year, due to seasonality patterns typical for certain of our procedures, or when they are away from their practices for various reasons;
- our ability to realize commercialized products from the licensing and distribution arrangements and other partnerships into which we have entered and will in the future enter; and
- the impact of fluctuations in foreign currency exchange rates, as most of our sales internationally are denominated in the local currency of the country in which we sell our products.

Further, we have made and expect to continue to make significant investments in our global sales force, marketing programs, research and development (R&D) activities, clinical studies, and general and administrative infrastructure. FDA-approved investigational device exemption (IDE) or investigational new drug (IND) studies and new product development programs in our industry are expensive. Our operating expenses have increased significantly following our acquisition of Avedro, Inc. (Avedro), and we have also incurred additional construction costs related to our new facility in Aliso Viejo, California (Aliso Facility), as well as expansions of our existing facilities in San Clemente, California and Burlington, Massachusetts.

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.

## Components of Results of Operations

### *Net Sales*

We currently operate in one reportable segment and net sales are generated primarily from sales of our *iStent* family of products and sales of *Photrexa* and other associated drug formulations, as well as our proprietary bioactivation systems and royalty income. Revenue is recognized when control of the promised goods or services is transferred to the customer in an amount that reflects the consideration to which we expect to be entitled in exchange for those products or services.

We sell the majority of our products through a direct sales organization in the United States. Internationally, we sell our products primarily through direct sales subsidiaries in seventeen countries and through independent distributors in certain countries in which we do not have a direct presence or maintain a modest commercial presence. The primary end-user customers for our products are surgery centers, hospitals and physician private practices.

While net sales may increase as we expand our global sales and marketing infrastructure and continue to increase awareness of our products by expanding our sales base and increasing our marketing efforts, historically our net sales within a fiscal year have been impacted seasonally, as demand for U.S. ophthalmic procedures is typically softer in the first quarter and stronger in the fourth quarter of a given year. However, we did not experience the same seasonality pattern in 2021 due in part to the COVID-19 pandemic. In 2022, we saw the return of some seasonality patterns, however traditional U.S. revenue patterns were disrupted as a result of the CMS reimbursement cuts. The effect of COVID-19 and other macroeconomic conditions, including higher interest rates and foreign exchange rate fluctuations, on our commercial performance may continue into future reporting periods. The 2022 CMS physician fee and facility fee rate decreases, which were effective in 2022 and will continue into 2023 have also disrupted traditional U.S. customer ordering patterns and have resulted in our customers' trialing of competitive products, causing reduced U.S. Glaucoma sales volumes during 2022. Our U.S. Corneal Health sales have experienced modest negative impacts due to sporadic reimbursement challenges. Additionally, unfavorable foreign exchange rates and global COVID dynamics in certain geographies in which we operate have negatively impacted our sales during the year ended December 31, 2022.

In addition to the foregoing, we had commercialized our products for several years in the U.S. with few or no direct competitors. Other competitive products have now become available in the U.S. and globally that have impacted and may continue to impact adoption of or demand for our products. We are also aware of similar products being developed by third parties that could enter the market and increase the competitive pressures we face. These other products could achieve greater commercial acceptance or demonstrate better safety or effectiveness, clinical results, ease of use or lower costs than our products, which could adversely impact our net sales.

### *Cost of Sales*

Cost of sales reflects the aggregate costs to manufacture our products and includes raw material costs, labor costs, manufacturing overhead expenses and the effect of changes in the balance of reserves for excess and obsolete inventory.

We manufacture our *iStent* family of products at our facility in San Clemente, California using components manufactured by third parties. We manufacture our KXL systems at our manufacturing facilities in Burlington, Massachusetts, and we contract with third-party manufacturers in the U.S. and Germany to produce our *Photrexa* and other associated drug formulations. We currently intend to maintain our manufacturing facilities at our San Clemente and Burlington locations for the foreseeable future.

Due to the relatively low production volumes of our *iStent* family of products and our KXL systems compared to our potential capacity for those products, a significant portion of our per unit costs is comprised of manufacturing overhead expenses. These expenses include quality assurance, material procurement, inventory control, facilities, equipment and operations supervision and management.



Cost of sales includes a charge equal to a low single-digit percentage of worldwide net sales of certain *iStent* products, with a required minimum annual payment of \$0.5 million, which amount became payable to the Regents of the University of California (the University) in connection with our December 2014 agreement with the University related to a group of our U.S. patents (the Patent Rights). This ongoing product payment obligation changed as patent coverage on certain products has lapsed, and terminated entirely on the date the last of the Patent Rights expires, which was December 29, 2022.

Cost of sales includes amortization of the \$252.2 million developed technology intangible asset. For each of the years ended December 31, 2022, December 31, 2021 and December 31, 2020, the amortization expense was \$22.1 million.

Our future gross profit as a percentage of net sales, or gross margin, will be impacted by numerous factors including commencement of sales of products in our pipeline, or any other future products, which may have higher product costs. Our gross margin will also be affected by manufacturing or supply chain inefficiencies that we may experience as we attempt to manufacture our products on a larger scale, manufacture new products and change our manufacturing capacity or output. Additionally, our gross margin will continue to be affected by royalty expenses on current or future products associated with various licensing agreements. Our gross margin in future periods may also be impacted by other factors adversely affecting our net sales in future periods, including the impact of the COVID-19 pandemic, supply chain disruptions, the current macroeconomic environment, including inflationary pressures and fluctuations in foreign currency, and the impact of the reductions on payment rates for certain of our products and related services as a result of the 2023 Final Rules.

### ***Selling, General and Administrative***

Our selling, general and administrative (SG&A) expenses primarily consist of personnel-related expenses, including salaries, sales commissions, bonuses, fringe benefits and stock-based compensation for our executive, financial, marketing, sales, and administrative functions. Other significant SG&A expenses include marketing programs; advertising; post-approval clinical studies; conferences and congresses; travel expenses; costs associated with obtaining and maintaining our patent portfolio; professional fees for accounting, auditing, consulting and legal services; costs associated with our global enterprise systems; and allocated facility expenses.

We expect SG&A expenses to continue to grow as we increase our global sales and marketing infrastructure and general administration infrastructure. We also expect other non-employee-related costs, including sales and marketing program activities for new products, outside services and accounting and general legal costs to increase as our overall operations grow. The timing of these increased expenditures and their magnitude are primarily dependent on the commercial success and sales growth of our products, as well as on the timing of any new product launches and other potential business and operational activities.

### ***Research and Development***

Our R&D activities primarily consist of new product development projects, pre-clinical studies, IDE and IND studies, and other clinical trials. Our R&D expenses primarily consist of personnel-related expenses, including salaries, fringe benefits and stock-based compensation for our R&D employees; research materials; supplies and services; in-licenses, including event-based milestones; and the costs of conducting clinical studies, which include payments to investigational sites and investigators, clinical research organizations, consultants, and other outside technical services and the costs of materials, supplies and travel. We expense R&D costs as incurred. We expect our R&D expenses to continue to increase as we initiate and advance our development programs, including our expanding surgical and pharmaceutical development efforts and clinical trials across glaucoma, retinal disease and corneal health.

Completion dates and costs for our clinical development programs include seeking regulatory approvals and our research programs vary significantly for each current and future product candidate and are difficult to predict. As a result, while we expect our R&D costs to continue to increase for the foreseeable future, we cannot estimate with any degree of certainty the costs we will incur in connection with the development of our product candidates. We anticipate we will make determinations as to which programs and product candidates to pursue and how much funding to direct to

each program and product candidate on an ongoing basis in response to the scientific success of early research programs, results of ongoing and future clinical trials, the availability of funding resources, as well as ongoing assessments as to each current or future product candidate's commercial potential and our likelihood of obtaining necessary regulatory approvals. We are not currently able to fully track expenses by product candidate.

### ***In-process Research and Development***

IPR&D expenses for the year ended December 31, 2022 totaled \$10.0 million related to our iVeena licensing agreement previously discussed in *Recent Developments* above.

Our IPR&D expenses for the year ended December 31, 2021 relate to a \$5.0 million upon signing our exclusive licensing agreement with Attilaps Holdings, Inc. and a \$5.0 million payment upon signing our exclusive licensing agreement with Intratus, Inc.

### ***Litigation-related Settlement***

The \$30.0 million cash payments we received pursuant to the terms of a Settlement Agreement dated September 14, 2021 (Settlement Agreement) are included in litigation-related settlement as a reduction of operating expenses on the consolidated statements of operations in each respective year.

### ***Non-Operating Expense, Net***

Non-operating expense, net primarily consists of interest expense associated with our finance lease for our Aliso Facility and for our 2.75% convertible notes due 2027 (Convertible Notes), interest income derived from our short-term investments and unrealized gains and losses arising from exchange rate fluctuations on transactions denominated in a currency other than the U.S. dollar, primarily related to intercompany loans.

### ***Income Taxes***

Our tax provision is primarily comprised of state and foreign income taxes. Our net deferred tax liability of \$7.3 million at December 31, 2022 primarily represents the excess of our indefinite-lived deferred tax liabilities over our indefinite-lived deferred tax assets. We continue to provide a full valuation allowance against our other net deferred tax assets.

We record reserves for uncertain tax positions where we believe the ability to sustain the tax position does not reach a more likely than not threshold.

## **Results of Operations**

For discussion related to the results of operations and changes in financial condition for the year ended December 31, 2021 compared to the year ended December 31, 2020 refer to "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of our 2021 Annual Report on Form 10-K, which was filed with the United States Securities and Exchange Commission on February 28, 2022.

**Comparison of Years Ended December 31, 2022 and December 31, 2021**

	Year ended December 31,		% Increase
(in thousands)	2022	2021	(decrease)
<b>Statements of operations data:</b>			
Net sales	\$ 282,862	\$ 294,011	(4)%
Cost of sales	68,979	66,627	4 %
Gross profit	213,883	227,384	(6)%
Operating expenses:			
Selling, general and administrative	192,925	179,257	8 %
Research and development	123,271	100,999	22 %
In-process research and development	10,000	10,000	— %
Litigation-related settlement	(30,000)	(30,000)	— %
Total operating expenses	296,196	260,256	14 %
Loss from operations	(82,313)	(32,872)	150 %
Non-operating loss, net	(16,116)	(16,395)	(2)%
Income tax provision	766	326	135 %
Net loss	\$ (99,195)	\$ (49,593)	100 %

NM = Not Meaningful

*Net Sales*

Our net sales are generated primarily from sales of *iStent* family of products to customers and sales of *Photrex* and associated drug formulations as well as KXL systems to customers. Customers are primarily comprised of ambulatory surgery centers, hospitals and physician private practices, with distributors being used in certain international locations where we currently do not have a direct commercial presence.

Net sales for the years ended December 31, 2022 and December 31, 2021 were \$282.9 million and \$294.0 million, respectively, reflecting a decrease of \$11.1 million or 4%.

Net sales of glaucoma products in the United States were \$144.7 million and \$170.8 million for the years ended December 31, 2022 and December 31, 2021, respectively, decreasing by approximately 15%. This decrease is primarily due to lower volumes caused by the significantly reduced CMS physicians' fee that was implemented on January 1, 2022, which has disrupted traditional U.S. customer ordering patterns and has resulted in our customers' trialing of competitive products. Additionally, sales in the second half of 2021 were positively impacted by abnormally high demand for cataract and glaucoma procedures following the rollout of the COVID-19 vaccines and increasing normalized economic and operating conditions within certain markets in which we operated at that time.

International sales of glaucoma products for the years ended December 31, 2022 and December 31, 2021 were \$69.6 million and \$61.2 million, respectively, increasing by approximately 14%. The increase in international sales reflects broad-based growing demand in many key international markets for combined cataract and glaucoma procedures, the dollar-based results of which were substantially affected by unfavorable foreign exchange rates, primarily related to the Euro and Japanese Yen, during the year ended December 31, 2022 as compared to the year ended December 31, 2021.

Net sales of corneal health products were \$68.6 million and \$62.0 million for the years ended December 31, 2022 and December 31, 2021, respectively, increasing by 11%. Of the \$6.6 million increase in net sales generated by our corneal health products, \$5.6 million related to U.S. sales using direct sales operations, which was comprised of an increase of \$6.0 million of Photrex net sales partially offset by reductions of \$0.4 million in U.S. capital equipment sales. Additionally, corneal health sales for the year ended December 31, 2022 were positively impacted by higher realized average sales and continued new account starts. Our international corneal health sales increased \$1.0 million, in locations where we utilize distributors given we do not have a direct commercial presence.

### *Cost of Sales*

Cost of sales for the years ended December 31, 2022 and December 31, 2021 were \$69.0 million and \$66.6 million, respectively, reflecting an increase of approximately \$2.4 million or 4%. Our gross margin was approximately 76% for the year ended December 31, 2022 compared to approximately 77% for the year ended December 31, 2021. The variance from the prior year resulted primarily from an increase in the product mix of modestly lower margin products of international market sales and higher material costs due to the inflationary environment.

### *Selling, General and Administrative Expenses*

SG&A expenses for the years ended December 31, 2022 and December 31, 2021 were \$192.9 million and \$179.3 million, respectively, reflecting an increase of \$13.6 million or 8%.

Of the total \$192.9 million, we incurred approximately \$125.1 million of costs associated with commercial personnel and discretionary spending during the year ended December 31, 2022 as compared to \$112.4 million during the year ended December 31, 2021, with the increase primarily due to compensation and related employee expenses associated with our sales infrastructure in glaucoma and corneal health, along with increased travel, meetings and accompanying costs as business activities have reopened and expanded over the course of the last twelve months. We also incurred approximately \$67.8 million of costs associated with general and administrative personnel and discretionary spending during the year ended December 31, 2022 as compared to \$63.4 million during the year ended December 31, 2021, associated with our ongoing administrative functions and amortization of our right-of-use asset related to our long-term lease for the Aliso Facility.

### *Research and Development Expenses*

R&D expenses for the years ended December 31, 2022 and December 31, 2021 were \$123.3 million and \$101.0 million, respectively, reflecting an increase of \$22.3 million or 22%.

For the year ended December 31, 2022, we incurred \$80.4 million in core R&D expenses and \$42.8 million in clinical expenses, comprised of \$63.1 million in compensation and related employee expenses with the remaining \$60.2 million spent on the continued research and development, clinical studies, regulatory activities, quality assurance, clinical inventory and supplies for surgical glaucoma product candidates and pharmaceutical projects, such as a pharmaceutical therapeutic system for the treatment of keratoconus without the removal of the epithelium (often referred to as “epi-on”), *iDose* and our earlier stage programs for dry eye, presbyopia, retina and other therapeutic investments. For the year ended December 31, 2021, we incurred \$66.6 million in core R&D expenses and \$34.4 million in clinical expenses, comprised of \$50.1 million in compensation and related employee expenses with the remaining \$50.9 million spent on the abovementioned programs.

### *In-process Research and Development*

IPR&D expenses for the year ended December 31, 2022 totaled \$10.0 million related to our *iVeena* licensing agreement previously discussed in *Recent Developments* above.

IPR&D expenses for the year ended December 31, 2021 related to the amendment of our exclusive licensing agreement with Intratus, Inc. and our exclusive licensing agreement with Attillaps Holdings, Inc. We paid \$5.0 million upon signing of each of these agreements.

### *Litigation-related Settlement*

The \$30.0 million cash payments from the Settlement Agreement received during each of the years ended December 31, 2022 and December 31, 2021 are included in litigation-related settlement as a reduction of operating expenses on the consolidated statements of operations.

### *Non-Operating Expense, Net*

We had non-operating expense, net of \$16.1 million and \$16.4 million for the years ended December 31, 2022 and December 31, 2021, respectively. The change in non-operating expense, net of \$0.3 million primarily relates to increased interest income earned on investments, partially offset by recognition of unrealized foreign currency losses due to higher intercompany loan balances denominated in, and impacted by, unfavorable changes in foreign currency exchange rates and higher interest expense recognized related to the Convertible Notes and to the finance lease for our Aliso Facility.

### *Income Tax Provision*

Our effective tax rate for the year ended December 31, 2022 was (0.78)%. For the year ended December 31, 2022 and December 31, 2021, we recorded a provision for income taxes of \$0.8 million and \$0.3 million, respectively. For each of the years ended December 31, 2022 and December 31, 2021 our tax provision was primarily comprised of state and foreign income tax expense.

## **Liquidity and Capital Resources**

Our principal sources of liquidity are our existing cash, cash equivalents and short-term investments, and generally cash generated from operating, financing and investing activities. Our primary uses of cash have been for selling and marketing activities, general and administrative expenses, research and development programs, and capital expenditures.

The following table summarizes our cash and cash equivalents, short-term investments and selected working capital data as of December 31, 2022 and December 31, 2021 (in thousands):

	December 31, 2022	December 31, 2021
Cash and cash equivalents	\$ 119,525	\$ 100,708
Short-term investments	233,170	313,343
Accounts receivable, net	36,073	33,438
Inventory	37,841	23,011
Accounts payable	14,403	7,333
Accrued liabilities	57,956	56,027
Working capital <sup>(1)</sup>	371,500	422,766

(1) Working capital consists of total current assets less total current liabilities per our consolidated balance sheets

### **Main Sources of Liquidity**

We plan to fund our operations, commitments for capital expenditures and other short and long-term known contractual and other obligations using existing cash and investments and, to the extent available, cash generated from commercial operations. Our existing cash and investments include the remaining net proceeds from the Convertible Notes issued in June 2020 (after payment for the related capped call transactions), and the two \$30.0 million payments received from Ivantis, Inc. during each of the years ended December 31, 2022 and December 31, 2021, which are being used for working capital and general corporate purposes.

#### *Cash, Cash Equivalents, Short-term Investments and Restricted Cash*

Our cash, cash equivalents and short-term investments totaled approximately \$352.7 million and our restricted cash totaled approximately \$7.1 million.

#### *Cash Flow used in Operations*

For the twelve months ended December 31, 2022, our operating activities used \$33.1 million in net cash.

### *Senior Convertible Notes*

Our Convertible Notes may be converted at the option of the holders at the times and under the circumstances and at the conversion rate described in *Note 8* of the notes to our consolidated financial statements. As of December 31, 2022, none of the conditions allowing holders of the Convertible Notes to convert had been met. These conditions are measured each quarter. For example, if our trading price remains above 130% of the conversion price for at least 20 trading days during the 30 consecutive trading-day period ending on, and including, March 31, 2023, holders of the Convertible Notes would have the right to convert their Convertible Notes during the calendar quarter beginning April 1, 2023. Upon conversion, we will pay or deliver, as the case may be, cash, shares of our common stock or a combination of cash and shares of our common stock, at our election, in the manner and subject to the terms and conditions provided in the Indenture. Settling all or a portion of the conversion obligation in cash 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 seek to obtain additional financing in the future through other debt or equity financings. There can be no assurance that we will be able to obtain additional financing on terms acceptable to us, or at all and 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.

### ***Short-term Liquidity Requirements***

Our short-term liquidity requirements primarily consist of regular operating costs, interest payments related to our Convertible Notes, R&D project funding, capital expenditures as we continue the development of our facilities and office spaces, operating and financing lease obligations and other firm purchase commitments. As of December 31, 2022, we had net working capital of \$371.5 million, which indicates that our current assets are sufficient to cover our short-term liabilities.

### ***Long-term Liquidity Requirements***

Our long-term liquidity requirements primarily consist of interest and principal payments related to our Convertible Notes, capital expenditures for the development of our manufacturing facilities and office spaces, and long-term material cash requirements as described below. As demand grows for our products, we will continue to expand global operations to meet demand through investments in our manufacturing capabilities.

## **Material Cash Requirements**

The following table summarizes our material cash requirements, including commitments for capital expenditures and known contractual and other obligations as of December 31, 2022, and the amount required to satisfy those requirements in future periods.

(in thousands)	Payments due by period				
	Total	Less than	1 - 3 years	3 - 5 years	More than
		1 year			5 years
Operating and finance lease obligations	\$ 178,686	\$ 7,798	\$ 17,275	\$ 17,994	\$ 135,619
Interest payments on Convertible Senior Notes	35,578	7,906	15,813	11,859	—
Firm purchase commitments	40,047	38,049	1,998	—	—
Total	\$ 254,311	\$ 53,753	\$ 35,086	\$ 29,853	\$ 135,619

The Convertible Notes will mature on June 15, 2027, unless earlier converted, redeemed or repurchased in accordance with their terms. In addition to the amounts included in the table above, we will incur material cash obligations related to our Convertible Notes, unless we elect to deliver solely shares of our common stock to settle such conversion.

After funding the current operations of our commercial activities, the first planned use of our cash flow from operations is to provide capital funding for our R&D and clinical activities. In addition to investing in R&D and clinical activities, we expect to utilize cash for various capital expenditures including the expansion and enhancement of our facilities. We have made and expect to continue to make significant investments in our global sales force, marketing programs, research and development activities, clinical studies and general and administrative infrastructure. FDA-approved IDE and IND studies and new product development programs in our industry are expensive.

We believe that cash from operating, financing and investing activities, together with our cash and investment balances, will be sufficient to meet ongoing operations, capital expenditures, commitments, working capital requirements and other known contractual and other obligations and satisfy our liquidity requirements for at least the next 12 months and the foreseeable future.

## Cash Flows

Our historical cash outflows have primarily been associated with cash used for operating activities such as the expansion of our sales, marketing and R&D activities; purchase of and growth in inventory and other working capital needs; the acquisition of intellectual property; and expenditures related to equipment and improvements used to increase our manufacturing capacity, to improve our manufacturing efficiency and for overall facility expansion.

The following table is a condensed summary of our cash flows for the periods indicated:

(in thousands)	Year ended December 31,	
	2022	2021
Net cash (used in) provided by:		
Operating activities	\$ (33,083)	\$ 24,708
Investing activities	44,779	(58,232)
Financing activities	6,251	39,260
Exchange rate changes	(1,468)	(1,774)
Net increase in cash, cash equivalents and restricted cash	\$ 16,479	\$ 3,962

At December 31, 2022, our cash and cash equivalents were held for working capital purposes. We do not enter into investments for trading or speculative purposes. Our policy is to invest any cash in excess of our immediate requirements in investments designed to preserve the principal balance and provide liquidity.

## Operating Activities

In the year ended December 31, 2022 our operating activities used \$33.1 million and for the year ended December 31, 2021 our operating activities provided \$24.7 million.

For the year ended December 31, 2022, our net cash used in operating activities reflected our net loss of \$99.2 million, adjusted for non-cash items of \$79.6 million, primarily consisting of stock-based compensation expense of \$38.6 million, depreciation of \$6.7 million, amortization of intangible assets of \$24.9 million, amortization of lease right-of-use assets of \$4.4 million, and amortization of debt issuance costs of \$1.4 million. Additionally, changes in operating assets and liabilities were \$13.4 million, which resulted primarily from increases in accounts payable and accrued liabilities of \$7.2 million, and decreases in other assets of \$0.3 million, offset by increases in inventory of \$15.5 million, increases in accounts receivable of \$3.1 million and increases in prepaids and other current assets of \$1.7 million.

For the year ended December 31, 2021, our net cash used in operating activities reflected our net loss of \$49.6 million, adjusted for non-cash items of \$70.7 million, primarily consisting of stock-based compensation expense of \$30.1 million, depreciation \$4.7 million, amortization of intangible assets of \$24.9 million, amortization of lease right-

of-use assets of \$4.8 million, and amortization of debt issuance costs of \$1.4 million. Additionally, this was partially offset by changes in operating assets and liabilities of \$3.6 million, which resulted from increases in accounts payable and accrued liabilities of \$12.4 million and decreases in accounts receivable of \$1.7 million, partially offset by increases in inventory of \$7.7 million and prepaid expenses and other current assets of \$3.1 million.

### ***Investing Activities***

In the year ended December 31, 2022 our investing activities provided cash of \$44.8 million and for the year ended December 31, 2021 net cash from investing activities used approximately \$58.2 million.

In the year ended December 31, 2022, we used approximately \$59.3 million for purchases of short-term investments, approximately \$30.3 million for purchases of property and equipment, primarily related to our facilities in Aliso Viejo, California; Burlington, Massachusetts; and San Clemente, California; and approximately \$1.0 million related to investments in company-owned life insurance, and we received cash of approximately \$135.2 million from sales and maturities of short-term investments.

In the year ended December 31, 2021, we used approximately \$215.3 million for purchases of short-term investments, approximately \$47.8 million for purchases of property and equipment, primarily related to our facilities in Aliso Viejo, California and San Clemente, California; and approximately \$2.1 million related to investments in company-owned life insurance, and we received cash of approximately \$206.9 million from sales and maturities of short-term investments.

We expect to continue our increased levels of capital expenditures into 2023 as we continue expansion of our manufacturing capacity for current and new products, improve our manufacturing efficiency and for overall facility expansion.

### ***Financing Activities***

In the years ended December 31, 2022 and December 31, 2021 our financing activities provided \$6.3 million and \$39.3 million of net cash, respectively.

In the year ended December 31, 2022, we received \$9.2 million from the exercises of stock options and purchases of our common stock by employees pursuant to our Employee Stock Purchase Plan and used \$2.7 million for payment of employee taxes related to restricted stock unit vestings. Additionally, we received \$0.3 million in proceeds from our tenant improvement allowances of our Aliso Facility and paid \$0.5 million in principal on our finance lease.

In the year ended December 31, 2021, we received \$30.9 million from the exercises of stock options and purchases of our common stock by employees pursuant to our Employee Stock Purchase Plan and used \$3.7 million for payment of employee taxes related to restricted stock unit vestings. Additionally, we received \$12.7 million in proceeds from our tenant improvement allowances of our Aliso Facility and paid \$0.7 million in principal on our finance lease.

We do not have any significant off-balance sheet arrangements or holdings in variable interest entities.

## **Critical Accounting Policies and Significant Estimates**

Management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and related disclosure of contingent assets and liabilities, revenue and expenses at the date of the consolidated financial statements. Generally, we base our estimates on historical experience and on various other assumptions in accordance with GAAP that we believe to be reasonable under the circumstances. Actual results may differ materially from these estimates under different assumptions or conditions and such differences could be material to our financial position and results of operations.



While our significant accounting policies are more fully described below and in the Notes to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies to be most critical for fully understanding and evaluating our financial condition and results of operations.

### ***Revenue Recognition***

We derive our revenue from sales of our products in the United States and internationally. Customers are primarily comprised of ambulatory surgery centers, hospitals and physician private practices, with distributors being used in certain international locations where we do not have a direct commercial presence.

We concluded that one performance obligation exists for the majority of our contracts with customers which is to deliver products in accordance with our normal delivery times. Revenue is recognized when this performance obligation is satisfied, which is the point in time when we consider control of a product to have transferred to the customer. Revenue recognized reflects the consideration to which we expect to be entitled in exchange for those products or services. We have determined the transaction price to be the invoice price, net of adjustments that reduce revenue, which includes estimates of variable consideration for certain product returns and warranty replacements. We only recognize revenue when it is probable that we will collect the consideration we are entitled to in exchange for the goods transferred to a customer. This requires management to perform an assessment related to the probability of collecting the consideration. The assessment can contain judgment when it is performed for customers with declining credit conditions or those with no history or a limited history of product sales with us.

We offer volume-based rebate agreements to certain customers and, in these instances, we provide a rebate (in the form of a credit memo) at the contract's conclusion, if earned by the customer. In such cases, the transaction price is allocated between our delivery of product and the issuance of a rebate at the contract's conclusion for the customer to utilize on prospective purchases. The performance obligation to issue a customer's rebate, if earned, is transferred over time and our method of measuring progress is the output method, whereby the progress is measured by the estimated rebate earned to date over the total rebate estimated to be earned over the contract period. The provision for volume-based rebates is estimated based on customers' contracted rebate programs and the customers' projected sales levels. We periodically monitor our customer rebate programs to ensure the rebate allowance is fairly stated. Our rebate allowance is included in accrued liabilities in the consolidated balance sheets and estimated rebates accrued were not material during the periods presented.

Additionally, we have performance obligations related to certain customers' right to a future discount on single dose pharmaceutical purchases in the U.S., as well as voluntary patient assistance programs to provide financial assistance to qualified patients. Each of these performance obligations is expected to be recognized when the customer or patient elects to utilize the discount, which is generally within one year. The impact of these programs on revenue were not material for the periods presented.

Customers are not granted specific rights of return; however, we may permit returns of certain products from customers if such product is returned in a timely manner and in good condition. We generally provide a warranty on our products for one year from the date of shipment, and offer an extended warranty for our KXL systems. Any product found to be defective or out of specification will be replaced or serviced at no charge during the warranty period. Estimated allowances for sales returns and warranty replacements are recorded at the time of sale of the product and are estimated based upon the historical patterns of product returns matched against sales, and an evaluation of specific factors that may increase the risk of product returns. Product returns and warranty replacements to date have been consistent with amounts reserved or accrued and have not been significant. If actual results in the future vary from our estimates, we will adjust these estimates which would affect net product revenue and earnings in the period such variances become known.

### ***Stock-Based Compensation Expense***

Stock-based compensation expense for a stock option award is measured at the date of grant, based on the estimated fair value of the award using the Black-Scholes option pricing model. The estimation of the fair value of each stock-based option grant or issuance on the date of grant is impacted by numerous assumptions by management,

including but not limited to expected stock price volatility over the term of the awards and the expected term of stock options. Our stock options have characteristics significantly different from those of traded options, and changes in the assumptions can materially affect the fair value estimates.

Stock-based compensation expense for a restricted stock unit (RSU) award is measured at the date of grant, based on the fair value of the award which is the closing price of our common stock on the date of grant.

For awards that vest based on service conditions, we use the straight-line method to recognize compensation expense over the respective service period. For awards that contain performance conditions, we determine the appropriate amount to expense based on the probable achievement of performance targets, which requires judgment, and which may include forecasting the achievement of future specified targets. At the date performance conditions are determined to be probable of achievement, we record a cumulative expense catch-up, with remaining expense amortized over the remaining service period. Throughout the performance period, we re-assess the estimated performance and update the number of performance-based awards that we believe will ultimately vest.

If factors change and we employ different assumptions, stock-based compensation expense may differ significantly from what we have recorded in the past. If there is a difference between the assumptions used in determining stock-based compensation expense and the actual factors which become known over time, we may change the input factors used in determining stock-based compensation expense for future grants. These changes, if any, may materially impact our results of operations in the period such changes are made. Forfeitures are estimated at the time of grant based on historical experience, and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

#### **Recent Accounting Pronouncements**

For a description of recent accounting pronouncements, see *Note 2* of the notes to our consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

## ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

### *Interest Rate Risk*

We are exposed to market risks in the ordinary course of our business. Our cash and cash equivalents include cash in readily available checking and money market accounts, as well as certificates of deposit. These securities are not dependent on interest rate fluctuations that could cause the principal amount of these assets to fluctuate and thus do not pose any interest rate risk to us. While we believe our cash and cash equivalents do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value.

In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits.

### *Foreign Currency Exchange Risk*

We have foreign currency risks related to our revenue and operating expenses denominated in currencies other than the U.S. dollar. Increases or decreases in our foreign-denominated revenue from movements in foreign exchange rates are often partially offset by the corresponding increases or decreases in our foreign-denominated operating expenses.

To the extent that our international operations grow, our risks associated with fluctuation in currency rates will become greater, and we will continue to assess our approach to managing this risk. In addition, currency fluctuations or a weakening U.S. dollar can increase the costs of our international operations. To date, we have not entered into any foreign currency hedging contracts although we may do so in the future.

A hypothetical 10% increase or decrease in the value of foreign exchange rates relative to the U.S. dollar as of December 31, 2022 would have had an immaterial impact on our net loss.

## **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

### **Index to Consolidated Financial Statements**

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## **Report of Independent Registered Public Accounting Firm**

To the Stockholders and the Board of Directors of Glaukos Corporation

### **Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Glaukos Corporation (the Company) as of December 31, 2022 and 2021, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2022, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2022, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 24, 2023 expressed an unqualified opinion thereon.

### **Adoption of ASU No. 2020-06**

As discussed in Note 8 to the consolidated financial statements, the Company changed its method for accounting for convertible debt in 2021 due to the adoption of Accounting Standards Update (ASU) No. 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity.

### **Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

### **Critical Audit Matter**

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

***Identification and classification of revenue related incentive programs***

*Description of  
the Matter*

As discussed in Note 2 of the consolidated financial statements, the Company derives its revenue from sales of its products in the United States and internationally. The Company has determined the transaction price to be the invoice price, net of adjustments that reduce revenue, which included estimates of volume-based rebates, variable consideration for product returns and warranty replacements and other discounts and incentives that reduce revenue.

Auditing the Company's net sales was challenging, specifically related to the effort required to evaluate the completeness of management's identification of incentive programs and whether the incentives were recognized and properly classified. This included judgmentally assessing factors including evaluation of contractual terms, incentives offered, and the proper classification

*How We  
Addressed the  
Matter in Our  
Audit*

We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the Company's process of recording revenue from sales of its products, including controls over the identification, review and approval of incentive programs and classification. We also tested management's controls related to the completeness and accuracy of data utilized in the controls.

To test management's identification, recognition and classification for customer incentive programs, our audit procedures included, among others, inquiries of sales representatives and other members of management and obtained confirmations from sales representatives to validate the completeness of customer incentive programs and revenue contracts provided to the finance and accounting department. We performed testing of a sample of transactions to assess the appropriateness of the classification. We also performed procedures to analyze trends in gross margin, cost of sales, and selling, general, and administrative costs. To test completeness of the population of customer incentive programs, we also examined credit memos issued subsequent to year end. For each material program identified, we tested classification of the incentive program.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2006.

Irvine, California

February 24, 2023

# Glaukos Corporation

## Consolidated Balance Sheets

(in thousands, except par values)

	December 31,	
	2022	2021
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 119,525	\$ 100,708
Short-term investments	233,170	313,343
Accounts receivable, net	36,073	33,438
Inventory	37,841	23,011
Prepaid expenses and other current assets	17,250	15,626
Total current assets	443,859	486,126
Restricted cash	7,078	9,416
Property and equipment, net	94,403	68,969
Operating lease right-of-use asset	25,826	28,142
Finance lease right-of-use asset	46,601	49,022
Intangible assets, net	307,869	332,781
Goodwill	66,134	66,134
Deposits and other assets	10,613	9,108
Total assets	\$ 1,002,383	\$ 1,049,698
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 14,403	\$ 7,333
Accrued liabilities	57,956	56,027
Total current liabilities	72,359	63,360
Convertible senior notes	281,400	280,026
Operating lease liability	28,905	29,650
Finance lease liability	72,172	72,699
Deferred tax liability, net	7,264	7,318
Other liabilities	10,278	9,494
Total liabilities	472,378	462,547
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000 shares authorized; no shares issued and outstanding as of December 31, 2022 and December 31, 2021	—	—
Common stock, \$0.001 par value; 150,000 shares authorized; 47,782 and 46,993 shares issued and 47,754 and 46,965 shares outstanding at December 31, 2022 and December 31, 2021, respectively	48	47
Additional paid-in capital	997,470	952,432
Accumulated other comprehensive (loss) income	(2,975)	15
Accumulated deficit	(464,406)	(365,211)
Less treasury stock (28 shares as of December 31, 2022 and December 31, 2021)	(132)	(132)
Total stockholders' equity	530,005	587,151
Total liabilities and stockholders' equity	\$ 1,002,383	\$ 1,049,698

See accompanying notes to consolidated financial statements.

**Glaukos Corporation**  
**Consolidated Statements of Operations**  
**(in thousands, except per share amounts)**

	Year ended December 31,		
	2022	2021	2020
Net sales	\$ 282,862	\$ 294,011	\$ 224,959
Cost of sales	68,979	66,627	91,719
Gross profit	213,883	227,384	133,240
Operating expenses:			
Selling, general and administrative	192,925	179,257	171,401
Research and development	123,271	100,999	85,392
In-process research and development	10,000	10,000	—
Litigation-related settlement	(30,000)	(30,000)	—
Total operating expenses	296,196	260,256	256,793
Loss from operations	(82,313)	(32,872)	(123,553)
Non-operating expense:			
Interest income	2,375	1,288	2,379
Interest expense	(13,720)	(13,372)	(14,115)
Other (expense) income, net	(4,771)	(4,311)	2,975
Total non-operating expense	(16,116)	(16,395)	(8,761)
Loss before taxes	(98,429)	(49,267)	(132,314)
Income tax provision (benefit)	766	326	(11,966)
Net loss	\$ (99,195)	\$ (49,593)	\$ (120,348)
Basic and diluted net loss per share	\$ (2.09)	\$ (1.07)	\$ (2.70)
Weighted-average shares outstanding used to compute basic and diluted net loss per share	47,444	46,423	44,497

See accompanying notes to consolidated financial statements.



**Glaukos Corporation**  
**Consolidated Statements of Comprehensive Loss**  
**(in thousands)**

	Year ended December 31,		
	2022	2021	2020
Net loss	\$ (99,195)	\$ (49,593)	\$ (120,348)
Other comprehensive loss:			
Foreign currency translation gain (loss)	985	781	(691)
Unrealized (loss) gain on short-term investments	(3,975)	(1,770)	365
Other comprehensive loss	(2,990)	(989)	(326)
Total comprehensive loss	\$ (102,185)	\$ (50,582)	\$ (120,674)

See accompanying notes to consolidated financial statements.

# Glaukos Corporation

## Consolidated Statements of Stockholders' Equity

(in thousands)

	Common stock		Additional	Accumulated	Accumulated	Treasury stock		Total
	Shares	Amount	paid-in	other	deficit	Shares	Amount	equity
			capital	comprehensive				
				income (loss)				
<b>Balance at December 31, 2019</b>	43,530	\$ 44	\$ 861,740	\$ 1,330	\$ (189,710)	(28)	\$ (132)	\$ 673,272
Common stock issued under stock plans	1,745	1	20,334	—	—	—	—	20,335
Equity component of convertible senior notes, net of transaction costs of \$3,267 and taxes of \$12,891	—	—	81,554	—	—	—	—	81,554
Purchase of capped calls related to issuance of convertible senior notes	—	—	(35,679)	—	—	—	—	(35,679)
Stock-based compensation	—	—	48,641	—	—	—	—	48,641
Other comprehensive loss	—	—	—	(326)	—	—	—	(326)
Net loss	—	—	—	—	(120,348)	—	—	(120,348)
<b>Balance at December 31, 2020</b>	45,275	\$ 45	\$ 976,590	\$ 1,004	\$ (310,058)	(28)	\$ (132)	\$ 667,449
Common stock issued under stock plans	1,718	2	27,249	—	—	—	—	27,251
Stock-based compensation	—	—	30,146	—	—	—	—	30,146
Effect of adoption of ASU 2020-06	—	—	(81,553)	—	(5,560)	—	—	(87,113)
Other comprehensive loss	—	—	—	(989)	—	—	—	(989)
Net loss	—	—	—	—	(49,593)	—	—	(49,593)
<b>Balance at December 31, 2021</b>	46,993	\$ 47	\$ 952,432	\$ 15	\$ (365,211)	(28)	\$ (132)	\$ 587,151
Common stock issued under stock plans	789	1	6,477	—	—	—	—	6,478
Stock-based compensation	—	—	38,561	—	—	—	—	38,561
Other comprehensive loss	—	—	—	(2,990)	—	—	—	(2,990)
Net loss	—	—	—	—	(99,195)	—	—	(99,195)
<b>Balance at December 31, 2022</b>	47,782	\$ 48	\$ 997,470	\$ (2,975)	\$ (464,406)	(28)	\$ (132)	\$ 530,005

See accompanying notes to consolidated financial statements.

# Glaukos Corporation

## Consolidated Statements of Cash Flows

(in thousands)

	Year ended December 31,		
	2022	2021	2020
<b>Operating Activities</b>			
Net loss	\$ (99,195)	\$ (49,593)	\$ (120,348)
Adjustments to reconcile net loss to net cash (used in) provided operating activities:			
Depreciation	6,664	4,749	4,469
Amortization of intangible assets	24,912	24,912	24,912
Amortization of the fair market value inventory adjustment	—	—	24,712
Amortization of right-of-use lease assets	4,370	4,760	5,232
Amortization of debt issuance costs	1,373	1,373	364
Amortization of debt discount	—	—	5,610
Deferred income tax benefit	(54)	(1,029)	(12,176)
(Gain) loss on disposal of fixed assets	(24)	7	367
Stock-based compensation	38,561	30,146	46,477
Change in fair value of cash-settled stock options	—	—	(3,172)
Unrealized foreign currency losses (gains)	2,242	2,313	(1,202)
Amortization of premium on short-term investments	731	1,028	453
Other liabilities	785	2,465	4,538
Changes in operating assets and liabilities:			
Accounts receivable, net	(3,138)	1,700	2,243
Inventory	(15,472)	(7,703)	1,962
Prepaid expenses and other current assets	(1,720)	(3,054)	(5,033)
Accounts payable and accrued liabilities	7,210	12,448	(2,683)
Other assets	(328)	186	287
Net cash (used in) provided by operating activities	(33,083)	24,708	(22,988)
<b>Investing activities</b>			
Purchases of property and equipment	(30,265)	(47,785)	(6,935)
Purchases of short-term investments	(59,256)	(215,285)	(301,002)
Proceeds from sales and maturities of short-term investments	135,157	206,916	104,697
Proceeds from disposal of property and equipment	151	3	—
Investment in company-owned life insurance	(1,008)	(2,081)	(1,820)
Net cash provided by (used in) investing activities	44,779	(58,232)	(205,060)
<b>Financing activities</b>			
Proceeds from convertible senior notes	—	—	287,500
Payment of convertible senior notes transaction costs	—	—	(9,614)
Purchase of capped calls related to issuance of convertible senior notes	—	—	(35,679)
Proceeds from exercise of stock options	3,577	26,124	20,196
Share purchases under Employee Stock Purchase Plan	5,630	4,817	4,025
Payments of employee taxes related to vested restricted stock units	(2,730)	(3,690)	(3,886)
Proceeds from tenant improvement allowance	301	12,668	—
Principal paid on finance lease	(527)	(659)	—
Net cash provided by financing activities	6,251	39,260	262,542
Effect of exchange rate changes on cash and cash equivalents	(1,468)	(1,774)	(88)
Net increase in cash, cash equivalents and restricted cash	16,479	3,962	34,406
Cash, cash equivalents and restricted cash at beginning of period	110,124	106,162	71,756
Cash, cash equivalents and restricted cash at end of period	\$ 126,603	\$ 110,124	\$ 106,162
<b>Supplemental schedule of noncash investing and financing activities</b>			
Purchases of property and equipment included in accounts payable and accrued liabilities	\$ 3,797	\$ 2,263	\$ 641
<b>Supplemental disclosures of cash flow information</b>			
Taxes paid, net of refunds	\$ 522	\$ 272	\$ 484
Interest paid on convertible senior notes	\$ 7,906	\$ 7,907	\$ 4,041
Other interest paid	\$ 4,434	\$ 4,074	\$ 1,334

See accompanying notes to consolidated financial statements.

# Glaukos Corporation

## Notes to Consolidated Financial Statements

### Note 1. Organization and Basis of Presentation

#### *Organization and Business*

Glaukos Corporation (Glaukos or the Company), incorporated in Delaware on July 14, 1998, is an ophthalmic medical technology and pharmaceutical company focused on developing novel therapies for the treatment of glaucoma, corneal disorders, and retinal diseases. The Company developed Micro-Invasive Glaucoma Surgery (MIGS) to serve as an alternative to the traditional glaucoma treatment paradigm and launched its first MIGS device commercially in 2012. The Company also offers 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. The Company is developing a portfolio of platforms to support ongoing pharmaceutical and medical device innovations. Products or product candidates for 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, diabetic macular edema and retinal vein occlusion.

The accompanying consolidated financial statements include the accounts of Glaukos and its wholly-owned subsidiaries. The Company translates the financial statements of its foreign subsidiaries using end-of-period exchange rates for assets and liabilities and average exchange rates during each reporting period for results of operations. All significant intercompany balances and transactions among the consolidated entities have been eliminated in consolidation.

#### *Liquidity*

For the year ended December 31, 2022, the Company incurred a net loss of \$99.2 million and \$33.1 million of cash was used for operating activities and, as of December 31, 2022, the Company had an accumulated deficit of \$464.4 million. The Company has made and expects to continue to make significant investments in its global sales force, marketing programs, research and development activities, clinical studies and general and administrative infrastructure. FDA-approved studies and new product development programs in the Company's industry are expensive. The Company also expects to incur additional construction costs related to its facilities in Aliso Viejo, California; San Clemente, California; and Burlington, Massachusetts.

The Company's 2.75% convertible notes due 2027 (Convertible Notes) may be converted at the option of the holders at the times and under the circumstances and at the conversion rate described in *Note 8, Convertible Senior Notes*. As of December 31, 2022, none of the conditions allowing holders of the Convertible Notes to convert had been met.

The Company plans to fund its operations, capital funding and other liquidity needs using existing cash and investments and, to the extent available, cash generated from commercial operations. The Company's existing cash and investments include, in part, the net proceeds from the Convertible Notes issued in June 2020 (after payment for the related capped call transactions), and the two \$30.0 million payments made to the Company by Ivantis, Inc. during the years ended December 31, 2022 and December 31, 2021 pursuant to the terms of the Settlement Agreement, which the Company is using for working capital and general corporate purposes.

The consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. Management expects to continue to incur additional substantial losses in the foreseeable future as a result of the Company's operating activities.

## **Note 2. Summary of Significant Accounting Policies**

### ***Basis of Presentation***

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP).

### ***Use of Estimates***

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates, judgments and assumptions that affect the reported amounts in the consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates and assumptions used in the preparation of the accompanying consolidated financial statements under different assumptions and conditions.

The Company's consolidated financial statements as of and for the year ended December 31, 2022 reflect the Company's estimates of the impact of the macroeconomic environment, including the impact of inflation, higher interest rates, foreign exchange rate fluctuations and the COVID-19 pandemic. The duration and the scope of these conditions cannot be predicted; therefore, the extent to which these conditions will directly or indirectly impact the Company's business, results of operations and financial condition, is uncertain. The Company is not aware of any specific event or circumstance that would require an update to its estimates, judgments and assumptions or a revision of the carrying value of the Company's assets or liabilities as of the date of this filing.

### ***Segments***

The Company has one business activity and operates as one operating segment: the development and commercialization of ophthalmic therapies designed to treat glaucoma, corneal disorders and retinal diseases. The Company determined its operating segment on the same basis that it uses to evaluate its performance internally. The Company's chief operating decision-maker (CODM), its Chief Executive Officer, reviews its consolidated operating results for the purpose of allocating resources and evaluating financial performance.

### ***Cash, Cash Equivalents, Restricted Cash and Short-term Investments***

The Company invests its excess cash in marketable securities, including U.S. government agency bonds, U.S. government bonds, bank certificates of deposit, commercial paper, municipal bonds, corporate notes and asset-backed securities. For financial reporting purposes, liquid investment instruments purchased with an original maturity of three months or less are considered to be cash equivalents. Cash and cash equivalents are recorded at face value or cost, which approximates fair market value. The Company maintains cash balances in excess of amounts insured by the Federal Deposit Insurance Commission. Investments are stated at fair value as determined by quoted market prices. Investments are considered available for sale and, accordingly, unrealized gains and losses are included in accumulated other comprehensive loss within stockholders' equity.

The Company's entire investment portfolio, except for restricted cash, is considered to be available for use in current operations and, accordingly, all such investments are stated at fair value using quoted market prices and classified as current assets, although the stated maturity of individual investments may be one year or more beyond the balance sheet date. The Company did not have any trading securities or restricted investments at December 31, 2022 or December 31, 2021.

Realized gains and losses and declines in value, if any, judged to be other-than-temporary on available for sale securities, are reported in other expense, net. When securities are sold, any associated unrealized gain or loss previously reported as a separate component of stockholders' equity is reclassified out of stockholders' equity and recorded in the statements of operations in the period sold using the specific identification method. Accrued interest and dividends from investments are included in other expense, net. The Company periodically reviews its available for sale securities for

other than temporary declines in fair value below the cost basis, and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

The following table provides a reconciliation of cash and cash equivalents and restricted cash reported within the consolidated balance sheets that equate to the amount reported in the consolidated statement of cash flows as of December 31, 2022, December 31, 2021 and December 31, 2020 (in thousands):

	Year ended December 31,		
	2022	2021	2020
Cash and cash equivalents	\$ 119,525	\$ 100,708	\$ 96,596
Restricted cash	7,078	9,416	9,566
Cash, cash equivalents and restricted cash in the consolidated statement of cash flows	\$ 126,603	\$ 110,124	\$ 106,162

### ***Concentration of Credit Risk and Significant Customers***

Financial instruments, which potentially subject the Company to significant concentration of credit risk, consist primarily of cash, cash equivalents, short-term investments and accounts receivable. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits and management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. Additionally, the Company has established guidelines regarding investment instruments and their maturities which are designed to maintain preservation of principal and liquidity. The Company believes that the concentration of credit risk in its accounts receivable is mitigated by its credit evaluation process, relatively short collection terms and the level of credit worthiness of its customers. During the years ended 2022, 2021 and 2020, none of the Company's customers accounted for more than 10% of revenues.

### ***Accounts Receivable***

The Company sells its products directly to ambulatory surgery centers, hospitals, and physician private practices, with distributors being used in certain international locations where the Company does not have a direct commercial presence and the Company is exposed to credit losses primarily through sales of its products.

The Company's expected loss allowance methodology for accounts receivable is developed using historical collection experience, current and future economic and market conditions and periodic evaluation of customers' receivables balances. Management estimates the adequacy of the allowance by using relevant available information, from internal and external sources, relating to past events, current conditions and forecasts. Historical credit loss experience provides the basis for estimation of expected credit losses and are adjusted as necessary using the relevant information available. The allowance for credit losses is measured on a collective basis when similar risk characteristic exists. The Company has identified one portfolio segment based on evaluation of the following risk characteristics: geographic regions, product lines, default rates and customer specific factors.

Additionally, specific allowance amounts may be established to record the appropriate provision for customers that have a higher probability of non-payment. The Company charges off uncollectible receivables against the allowance when all attempts to collect the receivable have failed. The Company's allowance for credit losses represents management's estimate of current expected credit losses and totaled approximately \$1.3 million and \$1.4 million as of December 31, 2022 and December 31, 2021, respectively, and there were immaterial bad-debt write offs charged during the years ended December 31, 2022 and December 31, 2021.

As of December 31, 2022 and December 31, 2021 the Company evaluated the current and expected future economic and market conditions surrounding the macroeconomic environment, including the impact of inflation, higher interest rates, foreign exchange rate fluctuations and the COVID-19 pandemic as it relates to collectability of its accounts receivable and determined the estimate of expected credit losses was not materially impacted. The Company will continue to re-evaluate the estimate of credit losses related to the current macroeconomic environment in conjunction with its assessment of expected credit losses in subsequent quarters.

Additionally, no customers accounted for more than 10% of net accounts receivable as of December 31, 2022 or December 31, 2021.

### ***Inventory***

Inventory is valued at the lower of cost or net realizable value with cost being determined on a first-in, first-out basis. The Company periodically reviews inventory for potential impairment, estimated losses from obsolescence, material expirations or unmarketable inventory or excess inventory and writes down the cost of inventory to net realizable value at the time such determinations are made. Net realizable value is determined using the estimated selling price, in the ordinary course of business, less estimated costs to complete and dispose.

### ***Property and Equipment, Net***

Property and equipment is recorded at cost. Depreciation of property and equipment is generally provided using the straight-line method over the estimated useful lives of the assets, which range from three to five years. Leasehold improvements are amortized over their estimated useful life or the related lease term, whichever is shorter. Maintenance and repairs are expensed as incurred.

All long lived assets are reviewed for impairment in value when changes in circumstances indicate that an asset or asset group's carrying value may not be recoverable, based upon undiscounted future operating cash flows to be derived from their use, and appropriate losses are recognized and reflected in current earnings to the extent the carrying amount of an asset exceeds its estimated fair value, determined by the use of appraisals, discounted cash flow analyses or comparable fair values of similar assets. The Company did not record any impairment charges for the year ended December 31, 2022, December 31, 2021 or December 31, 2020.

### ***Intangible Assets***

Intangible assets with finite-lives include developed technology and customer relationships, which are amortized on a straight-line basis over their estimated useful lives, which range from five to eleven years. The Company reviews finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets or asset group may not be recoverable. When such an event occurs, management determines whether there has been impairment by comparing the anticipated undiscounted future net cash flows to the related asset group's carrying value. If the affected intangible assets are not recoverable, management estimates the fair value of the assets and would record an impairment loss if the carrying value of the assets exceeds the fair value.

Indefinite-lived intangible assets are comprised of IPR&D assets and are not amortized, but instead tested for impairment until the successful completion and commercialization, or abandonment, of the associated research and development efforts, at which point the IPR&D assets are either amortized over their estimated useful lives, or written-off immediately.

Refer to *Note 6, Intangible Assets and Goodwill* for more information on the Company's intangible assets.

### ***Goodwill***

Goodwill represents the excess of the cost over the fair value of net assets acquired from business combinations. If the Company determines the carrying value of a reporting unit exceeds its fair value, an impairment charge would be recognized and should not exceed the total amount of goodwill allocated to that reporting unit. The Company has one reporting unit and tests for impairment annually, on October 1 and in addition to that test, regularly assesses if an event or indicator of impairment has occurred which would require interim impairment testing. The Company's annual impairment test did not result in any impairment, and the Company has not identified any indicators of impairment through December 31, 2022 and consequently, no impairment charge was recorded during the year.

Refer to *Note 6, Intangible Assets and Goodwill* for more information on the Company's goodwill.

### ***Fair Value of Financial Instruments***

The carrying amounts of cash equivalents, accounts receivable, accounts payable, and accrued liabilities are considered to be representative of their respective fair values because of the short-term nature of those instruments.

Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability.

The valuation of assets and liabilities is subject to fair value measurements using a three-tiered approach and fair value measurements are classified and disclosed by the Company in one of the following three categories:

Level 1: Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;

Level 2: Quoted prices for similar assets and liabilities in active markets, quoted prices in markets that are not active, or inputs which are observable, either directly or indirectly, for substantially the full term of the asset or liability; and

Level 3: Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (i.e., supported by little or no market activity).

Assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurements. The Company reviews the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels for certain assets or liabilities within the fair value hierarchy. The Company did not have any transfers of assets and liabilities between the levels of the fair value measurement hierarchy during the years presented.

### ***Leases***

The Company determines if an arrangement is a lease at inception. As a lessee, right-of-use assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent an obligation to make lease payments arising from the lease. Right-of-use assets and lease liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. The Company estimates the incremental borrowing rate based on its debt, prevailing financial market conditions, peer company credit analyses, and management judgment. Operating and financing lease right-of-use assets also include any lease payments made at or before lease commencement and exclude any lease incentives received. The lease terms used to calculate the right-of-use asset and related lease liability include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for operating leases is recognized on a straight-line basis over the lease term as an operating expense while the expense for finance leases is recognized as amortization expense on right-of-use lease assets and interest expense using the accelerated interest method of recognition.

### ***Revenue Recognition***

The Company derives its revenue from sales of its products in the United States and internationally. Customers are primarily comprised of ambulatory surgery centers, hospitals and physician private practices, with distributors being used in certain international locations where the Company does not have a direct commercial presence.

The Company concluded that one performance obligation exists for the majority of its contracts with customers which is to deliver products in accordance with the Company's normal delivery times. Revenue is recognized when this performance obligation is satisfied, which is the point in time when the Company considers control of a product to have transferred to the customer. Revenue recognized reflects the consideration to which the Company expects to be entitled in exchange for those products or services. The Company has determined the transaction price to be the invoice price,



net of adjustments that reduce revenue, which included estimates of volume-based rebates, variable consideration for product returns and warranty replacements and other discounts and incentives that reduce revenue.

The Company recognizes revenue when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods it transfers to the customer. This requires management to perform an assessment related to the probability of collecting the consideration. The assessment can contain judgment when it is performed for customers with declining credit conditions or those with no history or a limited history of product sales with the Company.

The Company offers volume-based rebate agreements to certain customers and, in these instances, the Company provides a rebate (in the form of a credit memo) at the contract's conclusion, if earned by the customer. In such cases, the transaction price is allocated between the Company's delivery of product and the issuance of a rebate at the contract's conclusion for the customer to utilize on prospective purchases. The performance obligation to issue a customer's rebate, if earned, is transferred over time and the Company's method of measuring progress is the output method, whereby the progress is measured by the estimated rebate earned to date over the total rebate estimated to be earned over the contract period. The provision for volume-based rebates is estimated based on customers' contracted rebate programs and the customers' projected sales levels. The Company periodically monitors its customer rebate programs to ensure the rebate allowance is fairly stated. The Company's rebate allowance is included in accrued liabilities in the consolidated balance sheets and estimated rebates accrued were not material during the periods presented.

Additionally, the Company has performance obligations related to other discounts and incentives including certain customers' right to a future discount on single dose pharmaceutical purchases in the U.S., as well as voluntary patient assistance programs to provide financial assistance to qualified patients. Each of these performance obligations is expected to be recognized when the customer or patient elects to utilize the discount, which is generally within one year. Additionally, the Company has a performance obligation related to its extended warranty agreements with customers related to its KXL systems. The impact of these programs on revenue were not material for the periods presented.

Customers are not granted specific rights of return; however, the Company may permit returns of certain products from customers if such product is returned in a timely manner and in good condition. The Company generally provides a warranty on its products for one year from the date of shipment, and offers an extended warranty for its KXL systems. Any product found to be defective or out of specification will be replaced or serviced at no charge during the warranty period. Estimated allowances for sales returns and warranty replacements are recorded at the time of sale of the product and are estimated based upon the historical patterns of product returns matched against sales, and an evaluation of specific factors that may increase the risk of product returns. Product returns and warranty replacements to date have been consistent with amounts reserved or accrued and have not been significant. If actual results vary from the Company's estimates, the Company will adjust these estimates in the period such variances become known.

### ***Shipping and Handling Costs***

All shipping and handling costs are expensed as incurred and are charged to selling, general and administrative expense. Charges to customers for shipping and handling are credited to selling, general and administrative expense.

### ***Advertising Costs***

All advertising costs are expensed as incurred. Advertising costs incurred during the years ended December 31, 2022, December 31, 2021 and December 31, 2020 were approximately \$2.5 million, \$1.2 million and \$1.6 million, respectively.

### ***Income Taxes***

Income taxes are accounted for using an asset and liability approach that requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the financial reporting basis and the tax basis of the Company's assets and liabilities at the applicable tax rates, along with net operating loss (NOL) and tax credit carryovers. The Company records a valuation allowance against a portion of deferred tax assets to

reduce the net carrying value to an amount that it believes is more likely than not to be realized. Management has considered estimated taxable income and ongoing prudent and feasible tax planning strategies in assessing the amount of the valuation allowance. Based upon the weight of available positive and negative evidence, which includes the Company's historical operating performance and limited potential to utilize tax credit carryforwards, the Company has determined that it is more likely than not that the future realization of all or some of the deferred tax assets will not be achieved and a portion of its deferred tax assets should be offset by a valuation allowance. When the Company establishes or reduces the valuation allowance against its deferred tax assets, its provision for income taxes increases or decreases, respectively, in the period such determination is made.

The Company is required to file federal and state income tax returns in the United States and various other state jurisdictions. The Company also files income tax returns in the foreign countries in which its subsidiaries operate. The preparation of these income tax returns requires the Company to interpret the applicable tax laws and regulations in effect in such jurisdictions, which could affect the amount of tax paid.

Additionally, the Company follows an accounting standard addressing the accounting for uncertainty in income taxes that prescribes rules for recognition, measurement, and classification in the consolidated financial statements of tax positions taken or expected to be taken in a tax return.

### ***Research and Development Expenses***

Major components of research and development expense include personnel costs, preclinical studies, clinical trials and related clinical product manufacturing, materials and supplies, and fees paid to consultants. Research and development costs are expensed as goods are received or services are rendered. Costs to acquire technologies to be used in research and development that have not reached technological feasibility and have no alternative future use are also expensed as incurred.

At each financial reporting date, the Company accrues the estimated unpaid costs of clinical study activities performed during a period by third party clinical sites with whom the Company has agreements that provide for fees based upon the quantities of subjects enrolled and clinical evaluation visits that occur over the life of the study. The cost estimates are determined based upon a review of the agreements and data collected by internal and external clinical personnel as to the status of enrollment and subject visits, and are based upon the facts and circumstances known to the Company at each financial reporting date. If the actual performance of activities varies from the assumptions used in the cost estimates, the accruals are adjusted accordingly. There have been no material adjustments to the Company's prior period accrued estimates for clinical trial activities through December 31, 2022.

### ***Stock-Based Compensation***

The Company recognizes compensation expense for all stock-based awards granted to employees and nonemployees, including members of its board of directors, based on the grant date fair value of the award.

For stock-based awards with service conditions, the fair value of the awards is amortized on a straight-line basis over the requisite service period in which the awards are expected to vest. For stock-based awards with performance vesting conditions, stock-based compensation is recognized when it is considered probable that the performance conditions will be satisfied. At each reporting period, the Company re-assesses the probability of the achievement of the performance vesting conditions. Any change in stock-based compensation resulting from an adjustment in the vesting is treated as a cumulative catch-up in the period of adjustment.

### *Software Costs*

The Company capitalizes certain costs when it is determined that it is probable that the project will be completed, the software will be used to perform the function intended, and the preliminary project stage is completed. These capitalized costs are included in property and equipment, net within the consolidated balance sheets.

### *Comprehensive Loss*

All components of comprehensive loss, including net loss, are reported in the consolidated financial statements in the period in which they are recognized. Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on marketable securities and foreign currency translation adjustments.

### *Net Loss per Share*

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares that were outstanding for the period, without consideration for potentially dilutive common stock equivalents.

For periods when the Company realizes a net loss, no potentially dilutive common stock equivalents are included in the calculation of weighted average number of dilutive common stock equivalents as the effect of applying the treasury stock method is considered anti-dilutive.

For periods when the Company realizes net income, diluted net income per share is calculated by dividing the net income by the weighted average number of common shares plus the sum of the weighted average number of dilutive common stock equivalents outstanding for the period determined using the treasury stock method or if-converted method for convertible instruments. Common stock equivalents are comprised of stock options, outstanding and unvested RSUs under the Company's incentive compensation plans and shares issuable under the Company's Employee Stock Purchase Plan (ESPP) and, beginning January 1, 2021, shares convertible pursuant to the Convertible Notes.

The Company's computation of net loss per share is as follows (in thousands, except per share amounts):

	As of December 31,		
	2022	2021	2020
<b>Numerator:</b>			
Net loss - basic	\$ (99,195)	\$ (49,593)	\$ (120,348)
<b>Denominator:</b>			
Weighted average number of common shares outstanding - basic and diluted	47,444	46,423	44,497
Basic net loss per share	\$ (2.09)	\$ (1.07)	\$ (2.70)
Diluted net loss per share	\$ (2.09)	\$ (1.07)	\$ (2.70)

Potentially dilutive securities not included in the calculation of diluted net loss per share because to do so would be anti-dilutive were as follows (weighted outstanding common stock equivalent shares, in thousands):

	As of December 31,		
	2022	2021	2020
Convertible senior notes	5,125	5,125	—
Stock options outstanding	2,373	2,951	4,399
Unvested restricted stock units	934	740	526
Employee stock purchase plan	8	11	15
	8,440	8,827	4,940

The Company has 5,000,000 of authorized preferred stock issuable, and there is no preferred stock outstanding as of December 31, 2022 and December 31, 2021. Each share of common stock is entitled to one vote.

### ***Recently Adopted Accounting Pronouncements***

The Company has not adopted any recent accounting pronouncements that had a material impact on its consolidated financial statements.

### ***Recently Issued Accounting Pronouncements Not Yet Adopted***

The Company reviewed recently issued accounting pronouncements and concluded that they were either not applicable or not expected to have a significant impact to the consolidated financial statements.

## **Note 3. Balance Sheet Details**

### ***Short-term Investments***

Short-term investments consisted of the following (in thousands):

	At December 31, 2022				
	Maturity (in years)	Amortized cost or cost	Unrealized gains	Unrealized losses	Estimated fair value
U.S. government agency bonds	less than 3	\$ 88,478	\$ —	\$ (2,413)	\$ 86,065
U.S. government bonds	less than 2	52,991	—	(384)	52,607
Bank certificates of deposit	less than 1	17,500	3	(11)	17,492
Corporate notes	less than 3	41,464	—	(978)	40,486
Asset-backed securities	less than 2	21,656	—	(360)	21,296
Municipal bonds	less than 3	15,635	—	(411)	15,224
Total		\$ 237,724	\$ 3	\$ (4,557)	\$ 233,170

		At December 31, 2021			
	Maturity (in years)	Amortized cost or cost	Unrealized gains	Unrealized losses	Estimated fair value
U.S. government agency bonds	less than 3	\$ 123,803	\$ 8	\$ (540)	\$ 123,271
U.S. government bonds	less than 2	76,765	—	(240)	76,525
Bank certificates of deposit	less than 1	12,500	1	(9)	12,492
Commercial paper	less than 1	2,998	—	(1)	2,997
Corporate notes	less than 3	55,178	37	(183)	55,032
Asset-backed securities	less than 2	23,761	44	(31)	23,774
Municipal bonds	less than 3	19,350	—	(98)	19,252
Total		\$ 314,355	\$ 90	\$ (1,102)	\$ 313,343

At each reporting date, the Company performs an evaluation of impairment to determine if any unrealized losses are the result of credit losses. Impairment is assessed at the individual security level. Factors considered in determining whether a loss resulted from a credit loss or other factors include the Company's intent and ability to hold the investment until the recovery of its amortized cost basis, the extent to which the fair value is less than the amortized cost basis, the length of time and extent to which fair value has been less than the cost basis, the financial condition of the issuer, any historical failure of the issuer to make scheduled interest or principal payments, any changes to the rating of the security by a rating agency, any adverse legal or regulatory events affecting the issuer or issuer's industry, and any significant deterioration in economic conditions.

The credit-related portion of unrealized losses, and any subsequent improvements, are recorded in interest expense in the consolidated statements of operations through an allowance for credit losses. Unrealized gains and losses that are not credit-related are included in accumulated other comprehensive loss. Unrealized losses on available-for-sale debt securities as of December 31, 2022 and December 31, 2021 were not significant and were primarily due to changes in interest rates, including market credit spreads, and not due to increased credit risks associated with specific securities. Further, the Company does not intend to sell these investments and it is not more likely than not that the Company will be required to sell these investments before recovery of their amortized cost basis. Accordingly, the Company did not record an allowance for credit losses with these investments as of December 31, 2022 and December 31, 2021.

### ***Accounts Receivable, Net***

Accounts receivable consisted of the following (in thousands):

	December 31,	
	2022	2021
Accounts receivable	\$ 37,323	\$ 34,805
Allowance for credit losses	(1,250)	(1,367)
	\$ 36,073	\$ 33,438

### ***Inventory***

Inventory consisted of the following (in thousands):

	December 31,	
	2022	2021
Finished goods	\$ 13,742	\$ 6,495
Work in process	10,495	7,010
Raw material	13,604	9,506
	\$ 37,841	\$ 23,011

### ***Property and Equipment, Net***

Property and equipment consisted of the following (in thousands):

	December 31,	
	2022	2021
Buildings	\$ 874	\$ 874
Equipment	24,701	19,280
Furniture and fixtures	6,908	1,706
Leasehold improvements	60,621	6,152
Computer equipment and software	3,580	3,333
Land	7,068	7,068
Construction in progress	17,875	51,208
	121,627	89,621
Less accumulated depreciation and amortization	(27,224)	(20,652)
	\$ 94,403	\$ 68,969

Depreciation and amortization expense related to property and equipment was \$6.6 million, \$4.8 million and \$6.1 million for the years ended December 31, 2022, December 31, 2021 and December 31, 2020, respectively.

### ***Accrued Liabilities***

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2022	2021
Accrued bonuses	\$ 17,219	\$ 17,015
Accrued vacation benefits	4,475	4,196
Other accrued liabilities	36,262	34,816
	\$ 57,956	\$ 56,027

#### Note 4. Fair Value Measurements

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2022 and December 31, 2021, and indicate the fair value hierarchy of the valuation techniques utilized by the Company to determine such fair value (in thousands).

	At December 31, 2022			
	December 31, 2022	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
<b>Assets</b>				
Cash equivalents:				
Money market funds <sup>(i)</sup>	\$ 53,106	\$ 53,106	\$ —	\$ —
Available for sale securities:				
U.S. government agency bonds <sup>(ii)</sup>	86,065	—	86,065	—
U.S. government bonds <sup>(ii)</sup>	52,607	—	52,607	—
Bank certificates of deposit <sup>(ii)</sup>	17,492	—	17,492	—
Corporate notes <sup>(ii)</sup>	40,486	—	40,486	—
Asset-backed securities <sup>(ii)</sup>	21,296	—	21,296	—
Municipal bonds <sup>(ii)</sup>	15,224	—	15,224	—
Investments held for deferred compensation plans	8,419	—	8,419	—
Total Assets	\$ 294,695	\$ 53,106	\$ 241,589	\$ —
<b>Liabilities</b>				
Deferred compensation plans	\$ 8,178	—	8,178	—
Total Liabilities	\$ 8,178	\$ —	\$ 8,178	\$ —

(i) Included in cash and cash equivalents with a maturity of three months or less from date of purchase on the consolidated balance sheets.

(ii) Included in short-term investments on the consolidated balance sheets.

	At December 31, 2021			
	December 31, 2021	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
<b>Assets</b>				
Cash equivalents:				
Money market funds <sup>(i)</sup>	\$ 4,212	\$ 4,212	\$ —	\$ —
Available for sale securities:				
U.S. government agency bonds <sup>(ii)</sup>	123,271	—	123,271	—
U.S. government bonds <sup>(ii)</sup>	76,525	—	76,525	—
Bank certificates of deposit <sup>(ii)(iii)</sup>	12,492	—	12,492	—
Commercial paper <sup>(ii)</sup>	2,997	—	2,997	—
Corporate notes <sup>(ii)</sup>	55,032	—	55,032	—
Asset-backed securities <sup>(ii)</sup>	23,774	—	23,774	—
Municipal bonds <sup>(ii)</sup>	19,252	—	19,252	—
Investments held for deferred compensation plans	7,412	—	7,412	—
Total Assets	\$ 324,967	\$ 4,212	\$ 320,755	\$ —
<b>Liabilities</b>				
Deferred compensation plans	7,302	—	7,302	—
Total Liabilities	\$ 7,302	\$ —	\$ 7,302	\$ —

(i) Included in cash and cash equivalents with a maturity of three months or less from date of purchase on the consolidated balance sheets.

(ii) Included in short-term investments on the consolidated balance sheets.

- (iii) One bank certificate of deposit totaling \$5,000 (in thousands) is included in cash and cash equivalents on the consolidated balance sheets, as the investment has a maturity of three months or less from the date of purchase on the consolidated balance sheets.

Money market funds are highly liquid investments and are actively traded. The pricing information on these investment instruments is readily available and can be independently validated as of the measurement date. This approach results in the classification of these securities as Level 1 of the fair value hierarchy.

U.S. government agency bonds, U.S. government bonds, bank certificates of deposit, commercial paper, municipal bonds, corporate notes and asset-backed securities are measured at fair value using Level 2 inputs. The Company reviews trading activity and pricing for these investments as of each measurement date. Pursuant to the Company's deferred compensation plan (the Deferred Compensation Plan), the Company has also established a rabbi trust that serves as an investment to shadow the Deferred Compensation Plan liability. The investments of the rabbi trust and Deferred Compensation Plan liability consist of company-owned life insurance policies (COLIs) and the pricing on these investments can be independently evaluated. When sufficient quoted pricing for identical securities is not available, the Company uses market pricing and other observable market inputs for similar securities obtained from third party data providers. These inputs represent quoted prices for similar assets in active markets or these inputs have been derived from observable market data. This approach results in the classification of these securities as Level 2 of the fair value hierarchy.

There were no transfers between levels within the fair value hierarchy during the periods presented.

The Company did not have any assets or liabilities measured at fair value on a recurring basis within Level 3 fair value measurements as of December 31, 2022 and December 31, 2021.

### ***Convertible Senior Notes***

As of December 31, 2022 and December 31, 2021, the fair value of the Convertible Notes was \$331.9 million and \$341.8 million, respectively. The fair value was determined on the basis of the market prices observable for similar instruments and is considered Level 2 in the fair value hierarchy. See *Note 8, Convertible Senior Notes* for additional information.

### **Note 5. Leases**

The Company's leases have remaining non-cancelable lease terms of approximately one year to thirteen years, some of which include options to extend the leases for up to ten years. The exercise of lease renewal options is at the Company's sole discretion. In certain of the Company's lease agreements, the rental payments are adjusted periodically to reflect actual charges incurred for common area maintenance, landlord incentives and/or inflation.

The Company's office building lease in Aliso Viejo, California (Aliso Facility) is one property containing three existing office buildings, comprising approximately 160,000 rentable square feet of space, which was accounted for as a finance lease. The term of the Aliso Facility commenced on April 1, 2019 for expense recognition and continues for thirteen years. The lease agreement contains an option to extend the lease for two additional five year periods at market rates. The Company relocated its corporate administrative headquarters, along with certain laboratory, research and development and warehouse space, to the Aliso Facility in the second quarter of 2022.

The Company also leases two adjacent facilities located in San Clemente, California and a facility in Burlington, Massachusetts. The total leased square footage of the San Clemente facilities equals approximately 98,000 and the leases expire on May 31, 2030. Each San Clemente facility lease contains an option to extend the lease for one additional five-year period at market rates. The total leased square footage of the Burlington facility is approximately 60,000 square feet, and the lease expires on July 31, 2033. The Burlington facility lease contains an option to extend the lease for one additional five-year period at market rates.

The Company terminated its lease in Waltham, Massachusetts pursuant to a termination agreement during the first quarter of 2022.



The Company's remaining U.S.-based and foreign subsidiaries' leased office space totals less than 14,000 square feet.

The following table presents the maturity of the Company's operating and finance lease liabilities within the consolidated balance sheets:

Leases (in thousands)	Classification	December 31, 2022	December 31, 2021
<b>Assets</b>			
Operating	Operating lease right-of-use asset	\$ 25,826	\$ 28,142
Finance	Finance lease right-of-use asset	46,601	49,022
Total lease assets		<u>\$ 72,427</u>	<u>\$ 77,164</u>
<b>Liabilities</b>			
Current			
Operating	Accrued liabilities	\$ 430	\$ 1,010
Noncurrent			
Operating	Operating lease liability	28,905	29,650
Finance	Finance lease liability	72,172	72,699
Total lease liabilities		<u>\$ 101,507</u>	<u>\$ 103,359</u>

Note: As the implicit rates in the Company's leases are not readily available, the incremental borrowing rate was determined based on the information available at commencement date in determining the present value of lease payments.

For the year ended December 31, 2022 and December 31, 2021, the components of operating and finance lease expenses were as follows:

Lease Cost (in thousands)	Classification	Year Ended December 31, 2022	Year Ended December 31, 2021
<b>Fixed operating lease cost</b>			
	Cost of sales	\$ 1,090	\$ 1,340
	Research and development	1,929	1,030
	Selling, general and administrative expenses	1,077 <sup>(a)</sup>	2,049 <sup>(a)</sup>
<b>Finance lease cost</b>			
	Amortization of right-of-use asset included in Selling, general and administrative expenses	\$ 2,421	\$ 2,421
Finance lease cost	Interest expense on lease liability	\$ 4,347	\$ 4,074

(a) Includes short-term leases, which are immaterial.

The following table presents the maturity of the Company's operating and finance lease liabilities as of December 31, 2022:

<b>Maturity of Lease Liabilities (in thousands)</b>	<b>Operating Leases <sup>(a)</sup></b>	<b>Finance Leases <sup>(b)</sup></b>
2023	\$ 2,765	\$ 5,033
2024	3,406	5,184
2025	3,345	5,340
2026	3,362	5,500
2027	3,467	5,665
Thereafter	33,738	101,881
Total lease payments	\$ 50,083	\$ 128,603
Less: imputed interest	20,748	56,431
Total lease liabilities	\$ 29,335	\$ 72,172

<sup>(a)</sup> Operating lease payments include \$20.6 million related to options to extend lease terms that are reasonably certain of being exercised.

<sup>(b)</sup> Finance lease payments include \$75.8 million related to options to extend lease terms that are reasonably certain of being exercised.

The weighted-average remaining lease term and weighted-average discount rate related to the Company's operating and finance leases as of December 31, 2022 and December 31, 2021 were:

<b>Lease Term and Discount Rate</b>	<b>December 31, 2022</b>	<b>December 31, 2021</b>
Weighted-average remaining lease term (years)		
Operating leases	13.3	13.6
Finance leases	19.3	20.3
Weighted-average discount rate		
Operating leases	8.0 %	7.9 %
Finance leases	6.0 %	6.0 %

Supplemental cash flow information related to the Company's operating and finance leases was as follows:

<b>Other Information (in thousands)</b>	<b>Year Ended December 31, 2022</b>	<b>Year Ended December 31, 2021</b>
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	\$ 2,931	\$ 3,761
Right-of-use asset obtained in exchange for new operating lease	\$ 576	\$ —
Net right-of-use remeasurement of operating leases	\$ (1,007)	\$ 10,496
Interest paid for finance lease	\$ 4,347	\$ 4,074

## **Note 6. Intangible Assets and Goodwill**

### ***Intangible assets***

For the years ended December 31, 2022, December 31, 2021 and December 31, 2020, amortization expense related to the Company's finite-lived intangible assets was approximately \$22.1 million and \$2.8 million, recorded in cost of sales and selling, general and administrative expenses, respectively, in the consolidated statement of operations.

### ***Goodwill***

The assessment of goodwill by reporting unit is performed annually, in the fourth quarter, or more frequently if events or circumstances indicate the carrying value may no longer be recoverable and that an impairment loss may have occurred. During this annual assessment, the Company considered the current and expected future economic and market

conditions and its impact on the Company's reporting unit and concluded there was no goodwill impairment as of December 31, 2022.

The following table presents the composition of the Company's intangible assets and goodwill (in thousands):

	Weighted-Average Amortization Period (in years)	As of December 31, 2022			As of December 31, 2021		
		Gross Carrying Amount	Accumulated Amortization	Net Amount	Gross Carrying Amount	Accumulated Amortization	Net Amount
Developed technology	11.4	\$ 252,200	\$ (68,577)	\$ 183,623	\$ 252,200	\$ (46,485)	\$ 205,715
Customer relationships	5.0	14,100	(8,754)	5,346	14,100	(5,934)	8,166
Intangible assets subject to amortization		266,300	(77,331)	188,969	266,300	(52,419)	213,881
In-process research and development	Indefinite	\$ 118,900	—	118,900	118,900	—	118,900
Total		\$ 385,200	\$ (77,331)	\$ 307,869	\$ 385,200	\$ (52,419)	\$ 332,781
Goodwill	Indefinite	\$ 66,134	—	66,134	66,134	—	66,134

As of December 31, 2022, expected amortization expense for unamortized finite-lived intangible assets for the next five years and thereafter is as follows (in thousands):

	Amortization Expense
2023	\$ 24,912
2024	24,619
2025	22,092
2026	22,092
2027	22,081
Thereafter	73,173
Total amortization	\$ 188,969

Actual amortization expense to be reported in future periods could differ from these estimates as a result of asset impairments, acquisitions, or other facts and circumstances.

## Note 7. Revenue from Contracts with Customers

### Disaggregation of Revenue

The Company's revenues disaggregated by product category and geography, for the years ended December 31, 2022, December 31, 2021 and December 31, 2020 was as follows (in thousands):

	Year ended December 31,						Total		
	United States			International					
	2022	2021	2020	2022	2021	2020	2022	2021	2020
Glaucoma	\$ 144,661	\$ 170,796	\$ 133,719	\$ 69,577	\$ 61,181	\$ 45,644	\$ 214,238	\$ 231,977	\$ 179,363
Corneal Health	58,577	52,995	39,367	10,047	9,039	6,229	68,624	62,034	45,596
Total	\$ 203,238	\$ 223,791	\$ 173,086	\$ 79,624	\$ 70,220	\$ 51,873	\$ 282,862	\$ 294,011	\$ 224,959

## ***Contract Balances***

### ***Contract Assets***

Amounts are recorded as accounts receivable when the Company's right to consideration becomes unconditional. Payment terms on invoiced amounts are typically 30 days for glaucoma and corneal health products, though extended payment terms on corneal health products may be offered. However, the Company does not consider any significant financing components in customer contracts given the expected time between transfer of the promised products and the payment of the associated consideration is less than one year. As of December 31, 2022 and December 31, 2021, substantially all amounts included in accounts receivable, net on the consolidated balance sheets are related to contracts with customers.

Aside from the aforementioned contract assets, the Company does not have any contract assets given that the Company does not have any unbilled receivables and sales commissions on products are expensed within selling, general and administrative expenses within the consolidated statement of operations when incurred as any incremental cost of obtaining contracts with customers would have an amortization period of less than one year.

### ***Contract Liabilities***

Contract liabilities reflect consideration received from customers' purchases allocated to the Company's future performance obligations.

The Company has a performance obligation to issue a rebate to customers who may be eligible for a rebate at the conclusion of their contract term. This performance obligation is transferred over time and the Company's method of measuring progress is the output method, whereby the progress is measured by the estimated rebate earned to date over the total rebate estimated to be earned over the contract period. The Company's rebate allowance is included in accrued liabilities in the consolidated balance sheets and estimated rebates accrued were not material during the periods presented.

During the years ended December 31, 2022 and December 31, 2021, the Company did not recognize any revenue related to material changes in transaction prices regarding its contracts with customers and did not recognize any material changes in revenue related to amounts included in contract liabilities at the beginning of the period.

## **Note 8. Convertible Senior Notes**

Under ASU 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity* (ASU 2020-06), the Company accounts for its convertible senior notes as a single unit of accounting, a liability, because the Company concluded that there were no material conversion features that require bifurcation as a derivative under ASU 2020-06 and its convertible debt instruments were not issued at a substantial premium.

In June 2020, the Company issued \$287.5 million in aggregate principal amount of Convertible Notes pursuant to an indenture dated June 11, 2020, between the Company and Wells Fargo Bank, National Association, as trustee (the Indenture), in a private offering to qualified institutional buyers in accordance with Rule 144A under the Securities Act of 1933, as amended. The Convertible Notes are senior unsecured obligations of the Company and bear interest at a rate of 2.75% per year, payable semi-annually in arrears on June 15 and December 15 of each year, beginning on December 15, 2020. The Convertible Notes will mature on June 15, 2027, unless earlier converted, redeemed or repurchased in accordance with their terms. In connection with issuing the Convertible Notes, the Company received \$242.2 million in proceeds, after deducting fees and offering expenses and paying the cost of the capped call transactions described below.

The Convertible Notes may be converted at the option of the holders at any time prior to the close of business on the business day immediately preceding March 15, 2027, only under the following circumstances: (1) during any calendar quarter commencing after the calendar quarter ended on September 30, 2020 (and only during such calendar

quarter), if the last reported sale price of the Company's common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day; (2) during the five business day period immediately after any ten consecutive trading day period (the Measurement Period) in which the trading price (as defined in the Indenture) per \$1,000 principal amount of the Convertible Notes for each trading day of the Measurement Period was less than 98% of the product of (i) the last reported sale price of the Company's common stock and (ii) the conversion rate in effect on each such trading day; (3) with respect to any Convertible Notes the Company calls for redemption, at any time prior to the close of business on the business day immediately preceding the redemption date, even if the Convertible Notes are not otherwise convertible at such time; or (4) upon the occurrence of specified corporate events. On or after March 15, 2027 until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert all or any portion of their Convertible Notes, in multiples of \$1,000 principal amount, at the option of the holder regardless of the foregoing circumstances. Upon conversion, the Company will pay or deliver, as the case may be, cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock, at the Company's election, in the manner and subject to the terms and conditions provided in the Indenture. As of December 31, 2022, none of the conditions allowing holders of the Convertible Notes to convert had been met.

Interest expense relating to the Convertible Notes in the consolidated statements of operations for the years ended December 31, 2022, December 31, 2021 and December 31, 2020 are summarized as follows (in thousands):

	Year ended December 31,		
	2022	2021	2020
Contractual interest expense	\$ 7,906	\$ 7,906	\$ 4,370
Amortization of debt discount	—	—	5,610
Amortization of debt issuance costs	1,373	1,373	364
Total interest expense	<u>\$ 9,279</u>	<u>\$ 9,279</u>	<u>\$ 10,344</u>

The effective interest rate on the Convertible Notes for the years ended December 31, 2022, December 31, 2021 and December 31, 2020 was 3.2%.

At the time of issuance and in accordance with Accounting Standards Codification Topic 470, the embedded conversion feature of the Convertible Notes required bifurcation from the notes and was accounted for as an equity instrument classified to stockholders' equity, which resulted in recognizing \$81.6 million in additional paid-in capital during the year ended December 31, 2020. As of January 1, 2021, the Company early adopted ASU 2020-06 using the modified retrospective adoption approach, which removed the requirement of separating the embedded conversion feature classified within stockholders' equity from the Convertible Notes. The standard also required the Company to use the if-converted method in the calculation of diluted earnings per share. Accordingly, the Company reclassified the unamortized debt discount and corresponding debt issuance costs from its additional paid-in capital to its convertible notes within liabilities in the Consolidated Balance Sheets. The adoption of ASU 2020-06 as of January 1, 2021 resulted in an increase to accumulated deficit of \$5.5 million, a decrease to additional paid-in capital of \$81.6 million, a decrease in the deferred tax liability of \$2.2 million and an increase to convertible notes, net of \$89.2 million. Interest expense recognized in future periods will be reduced as a result of accounting for the convertible debt instrument as a single liability measured at its amortized cost. Lastly, the Company derecognized deferred income taxes associated with the Convertible Notes and adjusted the deferred tax liability associated with the embedded conversion feature and corresponding change in the valuation allowance.

As of December 31, 2022, December 31, 2021 and December 31, 2020 the Convertible Notes on the consolidated balance sheets represented the carrying amount of the liability component of the Convertible Notes, net of unamortized debt issuance costs, which are summarized as follows (in thousands):

	Year ended December 31,		
	2022	2021	2020
Convertible Notes	\$ 287,500	287,500	287,500
Less: Unamortized debt discount	—	—	(92,102)
Less: Unamortized debt issuance costs	(6,100)	(7,474)	(5,982)
Carrying amount of Convertible Notes	\$ 281,400	280,026	189,416

## Capped Call Transactions

In connection with the offering of the Convertible Notes, in June 2020 the Company entered into privately negotiated capped call transactions with certain financial institutions (the Option Counterparties) and used an aggregate \$35.7 million of the net proceeds from the Convertible Notes to pay the cost of the capped call transactions. The capped call transactions are expected generally to reduce potential dilution to the Company's common stock upon any conversion of the Convertible Notes or at the Company's election (subject to certain conditions) offset any cash payments the Company is 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 based on the cap price. The cap price of the capped call transactions is initially \$86.30 per share, which represents a premium of 100% over the last reported sale price of the Company's common stock on June 8, 2020, and is subject to certain adjustments under the terms of the capped call transactions. The capped calls have an initial strike price of approximately \$56.10 per share, subject to certain adjustments, which corresponds to the conversion option strike price in the Convertible Notes. The capped call transactions cover, subject to customary adjustments, the number of shares of common stock initially underlying the Convertible Notes (or approximately 5.1 million shares of the Company's common stock).

The capped call transactions are separate transactions that the Company entered into with the Option Counterparties, are not part of the terms of the Convertible Notes and will not change the holders' rights under the Convertible Notes. As the capped call transactions meet certain accounting criteria, the cost of the capped call transactions of \$35.7 million was recorded as a reduction in additional paid-in capital in the consolidated balance sheets and will not be remeasured to fair value as long as the accounting criteria continue to be met. As of December 31, 2022, the Company had not purchased any shares under the capped call transactions.

## Note 9. Stock-Based Compensation

The Company has three stock-based compensation plans (collectively, the Stock Plans)— the 2011 Stock Plan (the 2011 Stock Plan), the 2015 Omnibus Incentive Compensation Plan (the 2015 Stock Plan) and the ESPP. The 2015 Stock Plan permits grants of RSU awards. The Company no longer grants any awards under the 2011 Stock Plan.

The purpose of these Stock Plans is to provide incentives to employees, directors and nonemployee consultants. The maximum term of any stock options granted under the Stock Plans is 10 years. For employees and nonemployees, time-based stock options generally vest 25% on the first anniversary of the original vesting date, with the balance vesting monthly or annually over the remaining three years. Stock options are granted at exercise prices at least equal to the fair value of the underlying stock at the date of the grant.

For employees and nonemployees, generally, time-based RSU awards vest 25% on each of the first, second, third and fourth anniversaries of the grant date and in certain cases, vest one year after grant date.

The Compensation, Nominating and Governance Committee has approved the grant of performance-based equity awards (PBEAs) to the Company's named executive officers and certain other employees pursuant to the 2015 Stock Plan and include performance-based stock options and performance-based restricted stock units. These PBEAs will only vest upon the Compensation Committee's determination that pre-defined Company operational goals were satisfied.

The ESPP permits eligible employees to purchase shares of the Company's common stock, using contributions via payroll deductions of up to 15% of their earnings, at a price per share equal to 85% of the lower of the stock's fair market value on the offering date or purchase date. The ESPP is intended to qualify as an "employee stock purchase plan" under Section 423 of the Internal Revenue Code.

As of January 1, 2023, the Company has reserved an aggregate of 20.5 million shares of common stock for issuance under the 2015 Stock Plan, and 3.7 million shares of common stock for issuance under the ESPP.

### ***Valuation and Expense Recognition of Stock-Based Awards***

The Company accounts for the measurement and recognition of compensation expense for all share-based awards made to the Company's employees and nonemployees based on the estimated fair value of the awards.

The Company uses the Black-Scholes option-pricing model to estimate the fair value of time-based and performance-based stock options and look back options included as part of the ESPP. The determination of fair value using the Black-Scholes option-pricing model is affected by the estimated fair market value per share of the Company's common stock as well as assumptions regarding a number of complex and subjective variables, including expected stock price volatility, risk-free interest rate, expected dividends and expected option life and generally requires significant management judgment to determine.

*Risk-free interest rate.* The risk-free interest rate is equal to the U.S. Treasury Note interest rate for the comparable term for the expected option life as of the valuation date. If the expected option life is between the U.S. Treasury Note rates of two published terms, then the risk-free interest rate is based on the straight-line interpolation between the U.S. Treasury Note rates of the two published terms as of the valuation date.

*Expected dividend yield.* The expected dividend yield is based on the Company's history and expectation of dividend payouts. The Company has never declared or paid any cash dividends and does not presently plan to pay cash dividends in the foreseeable future.

*Expected volatility.* During the year ended December 31, 2022, the Company based the expected volatility on the historic volatility of its common stock. During the year ended December 31, 2021, the Company based the expected volatility on a weighted average of the historical volatility of its common stock and historical volatilities of a peer group of similar companies over the most recent period commensurate with the estimated expected term of the Company's stock options. As the Company had a limited history as a publicly traded entity and a lack of robust Company-specific historical and implied volatility data prior to 2021, during the year ended December 31, 2020, the expected volatility assumption was based on historical volatilities of a peer group of similar companies whose share prices were publicly available. The peer group was developed based on companies in the biotechnology industry.

*Expected term.* The Company has concluded that its stock option exercise history does not provide a reasonable basis upon which to estimate expected term, and therefore it uses the simplified method for estimating the expected term of stock option grants. Under this approach, the weighted-average expected term is presumed to be the average of the vesting term and the contractual term of the option.

*Fair value of common stock.* The Company has used the daily closing market prices in the determination of the fair value of its common stock.

*Forfeiture rate.* The Company reduces share-based compensation expense for estimated forfeitures. Forfeitures are estimated at the time of grant based on historical experience, and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

## Stock Options

### *Time-based stock options*

The following table summarizes time-based stock option activity under the 2011 Stock Plan and 2015 Stock Plan:

	Number of shares underlying options (in thousands)	Weighted- average exercise price per share	Weighted- average remaining contractual life (in years)	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2019	6,583	\$ 23.98	6.1	\$ 204,062
Granted	733	37.90		
Exercised	(1,403)	14.75		51,441
Canceled/forfeited/expired	(76)	42.13		
Outstanding at December 31, 2020	5,837	\$ 27.30	5.6	\$ 280,055
Granted	50	60.74		
Adjustments to certain prior year grants	(31)	33.38		
Exercised	(1,301)	20.05		73,913
Canceled/forfeited/expired	(142)	52.15		
Outstanding at December 31, 2021	4,413	\$ 29.01	4.9	\$ 72,944
Granted	202	54.99		
Exercised	(295)	12.12		11,190
Canceled/forfeited/expired	(32)	54.31		
Outstanding at December 31, 2022	4,288	\$ 31.35	4.3	\$ 60,960
Vested and expected to vest at December 31, 2022	4,003	\$ 30.54	4.1	\$ 59,797
Exercisable at December 31, 2022	3,774	\$ 29.24	3.8	\$ 59,499

The weighted average estimated grant date fair value per share of time-based stock options granted during the years ended December 31, 2022, December 31, 2021 and December 31, 2020 was \$25.43, \$43.43 and \$11.44, respectively.

The total fair value of time-based stock options that vested during the years ended December 31, 2022, December 31, 2021 and December 31, 2020 was \$3.6 million, \$9.7 million and \$20.3 million, respectively.

As of December 31, 2022 unamortized stock-based compensation expense attributable to time-based stock options was \$6.0 million and is to be recognized over the stock options' remaining vesting terms of approximately 4.0 years (1.7 years on a weighted average basis).

The fair value of each time-based option award is estimated on the date of grant using a Black-Sholes option pricing model applying the assumptions noted in the following table. The weighted average assumptions used to estimate the fair value of options granted to employees and non-employees were as follows:

	Year ended December 31,		
	2022	2021	2020
Risk-free interest rate	2.55 %	0.98 %	0.71 %
Expected dividend yield	0.0 %	0.0 %	0.0 %
Expected volatility	55.6 %	43.4 %	48.8 %
Expected term (in years)	5.97	5.71	6.01



### *Performance-based stock options*

The following table summarizes performance-based stock option activity under the 2011 Stock Plan and 2015 Stock Plan:

	Number of shares underlying options (in thousands)	Weighted- average exercise price per share	Weighted- average remaining contractual life (in years)	Aggregate intrinsic value (in thousands)
Outstanding at December 31, 2019	—	\$ —	—	\$ —
Granted	147	39.10		
Exercised	—	—		—
Canceled/forfeited/expired	—	—		
Outstanding at December 31, 2020	147	\$ 39.10	9.2	\$ 5,311
Adjustments to certain prior year grants	(16)	39.10		
Granted	—	—		
Exercised	(2)	39.10		63
Canceled/forfeited/expired	—	—		
Outstanding at December 31, 2021	129	\$ 39.10	8.2	\$ 692
Granted	282	55.18		
Exercised	—	—		—
Canceled/forfeited/expired	(18)	39.10		
Outstanding at December 31, 2022	393	\$ 50.63	8.7	\$ 509
Vested and expected to vest at December 31, 2022	145	\$ 48.53	8.4	\$ 273
Exercisable at December 31, 2022	83	\$ 44.57	7.9	\$ 250

Intrinsic value is calculated as the difference between the exercise price of the underlying options and the fair value of the common stock for the options that had exercise prices that were lower than the fair value per share of the common stock on the date of exercise.

The weighted average estimated grant date fair value per share of performance-based stock options granted during the years ended December 31, 2022 and December 31, 2020 was \$10.93 and \$18.03, respectively. No performance-based stock options were granted during the year ended December 31, 2021.

The total fair value of performance-based stock options that vested during the years ended December 31, 2022 and December 31, 2021 was \$0.4 million and \$0.6 million, respectively. No performance-based stock options vested during the year ended December 31, 2020.

As of December 31, 2022 unamortized stock-based compensation expense attributable to performance-based stock options was \$0.1 million and is to be recognized over the stock options' remaining vesting terms of approximately less than one year (0.3 years on a weighted average basis).

The fair value of each performance-based option award is estimated on the date of grant using a Black-Sholes option pricing model applying the assumptions noted in the following table. The weighted average assumptions used to estimate the fair value of options granted to employees and non-employees were as follows:

	2022	2021	Year ended December 31, 2020
Risk-free interest rate	2.38 %	n/a	0.76 %
Expected dividend yield	0.0 %	n/a	0.0 %
Expected volatility	55.6 %	n/a	48.6 %
Expected term (in years)	6.01	n/a	6.01

## Restricted Stock Units

The fair value of restricted stock unit (RSU) awards made to employees and nonemployees is equal to the closing market price of the Company's common stock on the grant date.

### *Time-based RSUs*

The following table summarizes the activity of unvested time-based RSUs under the Stock Plans during the years ended December 31, 2022 and December 31, 2021:

	Number of shares (in thousands)	Weighted- average grant date fair value
Unvested at December 31, 2020	949	\$ 40.89
Granted	536	74.33
Vested	(349)	41.18
Canceled/forfeited	(126)	52.93
Unvested at December 31, 2021	1,010	\$ 57.30
Granted	738	56.40
Vested	(362)	53.96
Canceled/forfeited	(118)	55.42
Unvested at December 31, 2022	1,268	\$ 57.92

The total fair value of time-based RSUs that vested during the years ended December 31, 2022, December 31, 2021 and December 31, 2020 was \$19.5 million, \$14.4 million and \$17.3 million, respectively.

As of December 31, 2022 unamortized stock-based compensation expense attributable to time-based RSUs was \$53.6 million and is to be recognized over the RSU's remaining vesting terms of approximately 4.0 years (2.7 years on a weighted average basis).

### *Performance-based RSUs*

The following table summarizes the activity of unvested performance-based RSUs under the Stock Plans during the years ended December 31, 2022 and December 31, 2021:

	Number of shares (in thousands)	Weighted- average grant date fair value
Unvested at December 31, 2020	39	\$ 39.10
Granted	147	85.94
Vested	(10)	39.10
Canceled/forfeited	—	—
Unvested at December 31, 2021	176	\$ 78.19
Granted	37	55.18
Vested	(37)	42.21
Canceled/forfeited	—	—
Unvested at December 31, 2022	176	\$ 66.77

The total fair value of performance-based RSUs that vested during the years ended December 31, 2022, December 31, 2021 and December 31, 2020 was \$1.6 million and \$0.4 million, respectively. No performance-based RSUs vested during the year ended December 31, 2020.

As of December 31, 2022 unamortized stock-based compensation expense attributable to performance-based RSUs was \$0.9 million and is to be recognized over the RSU's remaining vesting terms of approximately less than one year (0.6 years on a weighted average basis).

### All Share-Based Compensation Arrangements

The following table summarizes the allocation of stock-based compensation related to time-based and performance-based stock options and RSUs and includes Replacement Awards, as well as cash-settled stock options in the accompanying consolidated statements of operations (in thousands):

	Year ended December 31,		
	2022	2021	2020
Cost of sales	\$ 1,849	\$ 1,739	\$ 2,440
Selling, general & administrative	26,988	21,665	32,072
Research and development	9,724	6,742	8,793
Total	\$ 38,561	\$ 30,146	\$ 43,305

<sup>(i)</sup> Of the total stock-based compensation amount of \$43.3 million as of December 31, 2020 above, \$13.0 million related to the value attributable to the pre-combination services associated with Replacement Awards and a \$(3.2) million fair value adjustment was recorded related to cash-settled stock options, and the remainder of the liability of \$2.2 million related to the cash-settled options that was previously included in accrued liabilities was, as a result of the modification, reclassified to additional paid-in capital.

In the years ended December 31, 2022, December 31, 2021, and December 31, 2020, the related tax (expense)/benefit was \$(0.5) million, \$12.3 million and \$3.5 million, respectively, relating to stock-based compensation.

The total stock-based compensation cost capitalized in inventory was not material for the years ended December 31, 2022, December 31, 2021 and December 31, 2020, respectively.

### Note 10. Income Taxes

United States and foreign (loss) income before income taxes was as follows (in thousands):

	Year ended December 31,		
	2022	2021	2020
United States	\$ (101,316)	\$ (51,370)	\$ (134,096)
Foreign	2,887	2,103	1,782
Total	\$ (98,429)	\$ (49,267)	\$ (132,314)

The income tax provision (benefit) was as follows (in thousands):

	December 31,		
	2022	2021	2020
Current:			
Federal	\$ (240)	\$ —	\$ (949)
State	368	189	275
Foreign	693	1,162	715
	821	1,351	41
Deferred:			
Federal	14	264	(10,098)
State	(87)	(1,234)	(1,952)
Foreign	18	(55)	43
	(55)	(1,025)	(12,007)
Income tax provision (benefit)	\$ 766	\$ 326	\$ (11,966)

The reconciliations of the U.S. federal statutory tax expense to the combined effective tax provision (benefit) are as follows:

	Year ended December 31,		
(amounts in thousands)	2022	2021	2020
Statutory rate of tax benefit	\$ (20,670)	\$ (10,346)	\$ (27,713)
State income taxes, net of federal benefit	(2,558)	(3,395)	(4,674)
Permanent and other items	497	4,513	263
Stock-based compensation	493	(12,310)	(3,537)
Research credits	(7,700)	(5,408)	(5,082)
Uncertain tax positions	3,711	2,685	3,835
Change in tax rate	56	(802)	1,303
NOL Carryback Claim	—	—	(447)
Valuation allowance	26,937	25,389	24,086
Income tax provision (benefit)	\$ 766	\$ 326	\$ (11,966)

Significant components of the Company's net deferred tax assets at December 31, 2022 and December 31, 2021 are as follows (in thousands):

	December 31,	
	2022	2021
<b>Deferred tax assets:</b>		
Net operating loss carryforwards	\$ 92,158	\$ 100,464
Tax credits	20,978	16,968
Stock-based compensation	15,142	15,521
Reserves and accruals	10,410	10,241
Lease liability	24,749	25,188
Section 174 research costs capitalization	25,286	—
Other, net	2,344	2,120
<b>Total deferred tax assets</b>	<b>\$ 191,067</b>	<b>\$ 170,502</b>
<b>Deferred tax liabilities:</b>		
Depreciation and amortization	(61,404)	(67,641)
ROU lease asset	(17,645)	(18,747)
Inventory	—	(59)
<b>Total deferred tax liabilities</b>	<b>\$ (79,049)</b>	<b>\$ (86,447)</b>
<b>Valuation allowance</b>	<b>(119,282)</b>	<b>(91,373)</b>
<b>Net deferred tax liability</b>	<b>\$ (7,264)</b>	<b>\$ (7,318)</b>

Based on the weight of available evidence, management has established a valuation allowance for a portion of its deferred tax assets which it expects will not be realized on a more likely than not basis. The net change in the valuation allowance was \$27.9 million in 2022.

At December 31, 2022, the Company had approximately \$449.1 million, \$321.1 million and \$10.8 million of NOL carryforwards for federal, state and foreign purposes, respectively, available to offset future taxable income. Federal NOL carryforwards incurred prior to 2018 begin to expire in 2024, while federal NOL carryforwards of \$241.1 million will not expire but can only be used to offset 80 percent of future taxable income. State and foreign NOL carryforwards begin to expire in 2023.

At December 31, 2022, the Company had federal and state R&D credit carryforwards of \$40.4 million and \$22.3 million, respectively. Federal and \$4.3 million of state credits begin to expire in 2023, while \$18.0 million of state credits carry forward indefinitely.

Utilization of the NOL and tax credit carryforwards will be subject to annual limitations under IRC Section 382 and Section 383 due to several ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of NOL and tax credit carryforwards and other deferred tax assets that can be utilized to offset future taxable income and/or income tax liabilities. In general, all ownership changes as defined by IRC Section 382 result from transactions increasing ownership of certain stockholders in the stock of the Company by more than 50 percentage points over a three-year period.

A reconciliation of the beginning and ending amount of gross unrecognized tax benefits for the years ended December 31, 2022, December 31, 2021 and December 31, 2020 excluding interest and penalties, is as follows (in thousands):

	December 31,		
	2022	2021	2020
Balance at beginning of the year	\$ 25,816	\$ 22,803	\$ 15,076
Net addition for tax positions - prior years	679	505	4,987
Net additions for tax positions - current year	4,307	3,489	3,355
Subtractions from tax positions - prior years	(553)	(327)	(74)
Subtractions from tax positions - current year	(1,281)	(654)	(541)
Balance at end of the year	\$ 28,968	\$ 25,816	\$ 22,803

As of December 31, 2022, approximately \$2.4 million of unrecognized tax benefits would reduce the Company's annual effective tax rate if recognized.

The Company's policy is to recognize interest expense and penalties related to income tax matters as a component of its income tax provision (benefit). There was no material accrued interest and penalties associated with uncertain tax positions as of December 31, 2022, December 31, 2021 and December 31, 2020. Approximately, \$0.5 million of the Company's unrecognized tax benefits are expected to reverse over the next 12 months.

Due to the Company's NOL carryforwards, its federal and state income tax returns are open to examination by the Internal Revenue Service and other state taxing jurisdictions for all years since inception. Certain foreign statute of limitations began expiring in 2022.

On August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022, which includes a 15% minimum tax on the adjusted financial statement income of corporations with a three taxable year average annual adjusted financial statement income in excess of \$1 billion, a 1% excise tax on net stock repurchases made by publicly traded U.S. corporations and several tax incentives to promote clean energy. The alternative minimum tax and excise tax are effective in taxable years beginning after December 31, 2022. These tax law changes are not expected to significantly impact the Company's consolidated financial statements. The Company will continue to evaluate its impact as further information becomes available.

Beginning in 2022, the Tax Cuts and Jobs Act of 2017 requires taxpayers to capitalize and amortize R&D expenditures over five years for domestic research and 15 years for foreign research pursuant to Section 174 of the Internal Revenue Code of 1986, as amended. The increase in the Company's deferred tax assets is primarily related to the capitalization of R&D expenditures under Section 174.

There are no cumulative earnings in the Company's foreign subsidiaries as of December 31, 2022 that would be subject to U.S. income tax or foreign withholding tax. The Company plans to indefinitely reinvest any future earnings of its foreign subsidiaries.

## **Note 11. Employee Benefits**

### ***Defined Contribution Plan***

The Company sponsors a defined contribution plan pursuant to section 401(k) of the U.S. Internal Revenue Code that allows participating employees to contribute up to 100% of their salary, to an annual maximum of \$20,500 and \$19,500 in 2022 and 2021, respectively (\$27,000 and \$26,000 in 2022 and 2021, respectively, for employees over the age of 50). Through December 31, 2022, the Company has only made "qualified nonelective contributions" to maintain compliance with IRS regulations.

During the years ended December 31, 2022 and December 31, 2021, the Company contributed a \$0.50 match for every \$1.00 contributed by a participating employee up to 6% of plan-eligible earnings, with such Company

contributions becoming fully vested when participating employees reach the 3-year anniversary from their date of hire, giving credit for past service. For the years ended December 31, 2022 and December 31, 2021, Company contributions totaled approximately \$2.5 million and \$2.1 million, respectively.

During the first quarter of 2020, the Company contributed a \$0.50 match for every \$1.00 contributed by a participating employee up to 6% of plan-eligible earnings for a portion of the year. As a result of the COVID-19 pandemic, the Company instituted a number of cost saving initiatives, including temporarily ceasing Company contributions to participating employees' 401(k) plans, which the Company reinstated as of January 1, 2021. For the year ended December 31, 2020, Company contributions totaled approximately \$0.5 million.

### ***Deferred Compensation Plan***

Pursuant to the Company's deferred compensation plan (the Deferred Compensation Plan), eligible senior level employees are permitted to make elective deferrals of compensation to which they will become entitled in the future. The Company has also established a rabbi trust that serves as an investment to shadow the Deferred Compensation Plan liability. The investments of the rabbi trust consist of COLIs. The fair value of the Deferred Compensation Plan liability, included in other liabilities on the consolidated balance sheets, was approximately \$8.2 million and \$7.3 million as of December 31, 2022 and December 31, 2021, respectively, and the cash surrender value of the COLIs, included in deposits and other assets on the consolidated balance sheets, which reflects the underlying assets at fair value, was approximately \$8.4 million and \$7.4 million as of December 31, 2022 and December 31, 2021, respectively.

## **Note 12. Commitments and Contingencies**

### ***Secured Letters of Credit***

The Company has a letter of credit that is related to its Aliso Facility. The letter of credit is secured with an amount of cash held in a restricted account of approximately \$6.8 million and \$8.8 million as of December 31, 2022 and December 31, 2021, respectively. Beginning as of the first day of the thirty-seventh month of the lease term (which occurred during 2022), and on each twelve month anniversary thereafter, the letter of credit will be reduced by 20% until the letter of credit amount has been reduced to \$2.0 million.

The Company has other irrevocable standby letters of credit secured with approximately \$0.3 million of cash in a restricted account.

### ***Purchase Commitment***

As of December 31, 2022, the Company had noncancelable, firm purchase commitments of \$2.0 million due beyond one year.

### ***Regents of the University of California***

On December 30, 2014, the Company executed an agreement (the UC Agreement) with the Regents of the University of California (the University) to correct inventorship in connection with a group of the Company's U.S. patents (the Patent Rights) and to obtain from the University a covenant that it did not and would not claim any right or title to the Patent Rights and will not challenge or assist any others in challenging the Patent Rights. In connection with the UC Agreement, Glaukos agreed to pay to the University a low single-digit percentage of worldwide net sales of certain current and future products, including the Company's *iStent* products, with a required minimum annual payment of \$0.5 million. This ongoing product payment obligation has changed as patent coverage on certain products has lapsed, and terminated entirely on the date the last of the Patent Rights expires, which was December 29, 2022. For the years ended December 31, 2022, December 31, 2021 and December 31, 2020, the Company recorded approximately \$3.1 million, \$4.2 million and \$4.5 million, respectively, in cost of sales in connection with the product payment obligation.

### ***Indemnification***

In the ordinary course of business, the Company enters into agreements that may include indemnification

provisions. Pursuant to such agreements, the Company may indemnify, hold harmless and defend the indemnified parties for losses suffered or incurred by the indemnified party. Some of the provisions will limit losses to those arising from third-party actions. In some cases, the indemnification will continue after the termination of the agreement. The maximum potential amount of future payments the Company could be required to make under these provisions is not determinable. To date, the Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. The Company has also entered into indemnification agreements with its directors and officers that may require it to indemnify its directors and officers against liabilities that may arise by reason of their status or service as directors or officers to the fullest extent permitted by corporate law. The Company also has directors' and officers' insurance.

### Note 13. Business Segment Information

The Company has one business activity and operates as one operating segment: the development and commercialization of ophthalmic therapies designed to treat glaucoma, corneal disorders and retinal diseases. The Company determined its operating segment on the same basis that it uses to evaluate its performance internally. The Company's revenues disaggregated by revenue and product category are included in *Note 7, Revenue from Contracts with Customers*. The Company's chief operating decision-maker, its Chief Executive Officer, reviews its consolidated operating results for the purpose of allocating resources and evaluating financial performance.

	Property and equipment, net			Depreciation and amortization			Capital expenditures		
	As of December 31,			Year ended December 31,			Year ended December 31,		
	2022	2021	2020	2022	2021	2020	2022	2021	2020
United States	\$ 94,263	\$ 68,839	\$ 23,896	\$ 31,547	\$ 29,622	\$ 29,306	\$ 30,212	\$ 47,714	\$ 6,907
International	140	130	112	29	39	75	53	71	28
Total	\$ 94,403	\$ 68,969	\$ 24,008	\$ 31,576	\$ 29,661	\$ 29,381	\$ 30,265	\$ 47,785	\$ 6,935

### Note 14. Selected Quarterly Financial Information (Unaudited)

(in thousands, except per share amounts)	Three months ended			
	March 31, 2022	June 30, 2022	September 30, 2022	December 31, 2022
Net sales	\$ 67,681	\$ 72,685	\$ 71,269	\$ 71,227
Cost of sales	17,063	17,833	16,861	17,222
Gross profit	50,618	54,852	54,408	54,005
Operating expenses:				
Selling, general and administrative	43,949	49,900	47,149	51,927
Research and development	26,877	31,712	28,870	35,812
In-process research and development	—	10,000	—	—
Litigation-related settlement	(30,000)	—	—	—
Total operating expenses	40,826	91,612	76,019	87,739
Income (loss) from operations	9,792	(36,760)	(21,611)	(33,734)
Non-operating expense	(4,089)	(8,881)	(5,718)	2,572
Income tax provision (benefit)	326	(105)	247	298
Net income (loss)	\$ 5,377	\$ (45,536)	\$ (27,576)	\$ (31,460)
Net income (loss) per share <sup>(1)</sup> :				
Basic and diluted	\$ 0.11	\$ (0.96)	\$ (0.58)	\$ (0.66)



	Three months ended			
	March 31, 2021	June 30, 2021	September 30, 2021	December 31, 2021
(in thousands, except per share amounts)				
Net sales	\$ 67,968	\$ 78,093	\$ 74,710	\$ 73,240
Cost of sales	16,633	17,759	15,370	16,865
Gross profit	51,335	60,334	59,340	56,375
Operating expenses:				
Selling, general and administrative	41,921	45,300	44,470	47,566
Research and development	21,219	24,256	28,846	26,678
In-process research and development	—	5,000	5,000	—
Litigation-related settlement	—	—	(30,000)	—
Total operating expenses	63,140	74,556	48,316	74,244
(Loss) income from operations	(11,805)	(14,222)	11,024	(17,869)
Non-operating expense	(4,385)	(3,052)	(4,592)	(4,366)
Income tax provision	279	208	202	(363)
Net (loss) income	\$ (16,469)	\$ (17,482)	\$ 6,230	\$ (21,872)
Net (loss) income per share <sup>(1)</sup> :				
Basic and diluted	\$ (0.36)	\$ (0.38)	\$ 0.13	\$ 0.47

<sup>(1)</sup> Net income or loss per share is computed independently for each of the quarters presented. Therefore, the sum of the quarterly per-share amounts will not necessarily equal the annual per share amount.

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

## **ITEM 9A. CONTROLS AND PROCEDURES**

### **Evaluation of Disclosure Controls and Procedures**

The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our management, with the participation of our chief executive officer and our chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, our chief executive officer and our chief financial officer concluded that our disclosure controls and procedures were effective, at the reasonable assurance level, as of December 31, 2022.

### **Management’s Annual Report on Internal Control Over Financial Reporting and Attestation Report of the Registered Public Accounting Firm**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that the transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and our directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Our management, with the participation of our chief executive officer and our chief financial officer, conducted an evaluation of the effectiveness of our internal control over financial reporting as of the end of the period covered by this Annual Report on Form 10-K based on the framework in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, management concluded that the Company’s internal control over financial reporting was effective as of December 31, 2022.

Ernst & Young LLP, our independent registered public accounting firm, which audited the consolidated financial statements included in this Annual Report on Form 10-K, has issued an attestation report on our internal control over financial reporting. See Report of Independent Registered Public Accounting Firm below.

### **Changes in Internal Control over Financial Reporting**

There have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, during our fourth fiscal quarter of 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **Report of Independent Registered Public Accounting Firm**

To the Stockholders and the Board of Directors of Glaukos Corporation

### **Opinion on Internal Control Over Financial Reporting**

We have audited Glaukos Corporation's internal control over financial reporting as of December 31, 2022, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Glaukos Corporation (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2022, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2022 and 2021, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2022, and the related notes and our report dated February 24, 2023 expressed an unqualified opinion thereon.

### **Basis for Opinion**

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

### **Definition and Limitations of Internal Control Over Financial Reporting**

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Irvine, California

February 24, 2023

**ITEM 9B. OTHER INFORMATION**

None.

**ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS**

Not applicable.

## **PART III**

### **ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

We have adopted a written code of business conduct and ethics that applies to our directors, executive officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A current copy of the code is posted on the investor section of our web site, [www.glaukos.com](http://www.glaukos.com). To the extent required by rules adopted by the SEC and NYSE, we intend to promptly disclose future amendments to certain provisions of the code, or waivers of such provisions granted to executive officers and directors, in the Corporate Governance section of our Investor Relations web site at [investors.glaukos.com](http://investors.glaukos.com).

The remaining information required by this Item 10 will be included in our Proxy Statement for the 2023 Annual Meeting of Stockholders, which will be filed with the SEC no later than 120 days after the close of the fiscal year ended December 31, 2022, and is incorporated herein by reference.

### **ITEM 11. EXECUTIVE COMPENSATION**

The information required by this Item 11 will be included in our Proxy Statement for the 2023 Annual Meeting of Stockholders, which will be filed with the SEC no later than 120 days after the close of the fiscal year ended December 31, 2022, and is incorporated herein by reference.

### **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

The information required by this Item 12 will be included in our Proxy Statement for the 2023 Annual Meeting of Stockholders, which will be filed with the SEC no later than 120 days after the close of the fiscal year ended December 31, 2022, and is incorporated herein by reference.

### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

The information required by this Item 13 will be included in our Proxy Statement for the 2023 Annual Meeting of Stockholders, which will be filed with the SEC no later than 120 days after the close of the fiscal year ended December 31, 2022, and is incorporated herein by reference.

### **ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The information required by this Item 14 will be included in our Proxy Statement for the 2023 Annual Meeting of Stockholders, which will be filed with the SEC no later than 120 days after the close of the fiscal year ended December 31, 2022, and is incorporated herein by reference.

## **PART IV**

### **ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

(a) List of documents filed as part of this Annual Report on Form 10-K:

(1) Financial Statements

The financial statements included in Part II, Item 8 of this document are filed as part of this Annual Report on Form 10-K.

(2) Financial Statement Schedules

Schedules have been omitted because they are not applicable or the amounts are immaterial or the required information is presented in the financial statements or notes thereto.

(b) Exhibits

The exhibits listed in the Exhibit Index below are filed, furnished or incorporated by reference as part of this Annual Report on Form 10-K.

## INDEX TO EXHIBITS

Exhibit Number	Description
3.1	Restated Certificate of Incorporation of the Registrant (incorporated by referenced to Exhibit 3.1 to the Current Report on Form 8-K (File No. 001-37463) filed on June 30, 2015).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K (File No. 001-37463) filed on December 21, 2022).
4.1	Indenture, dated as of June 11, 2020, between Glaukos Corporation and Wells Fargo Bank, National Association, as trustee (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K (File No. 001-37463) filed on June 12, 2020).
4.2	Form of 2.75% Convertible Senior Notes due 2027 (included in Exhibit 4.1) (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K (File No. 001-37463) filed on June 12, 2020).
4.3	Description of Capital Stock of Glaukos Corporation (incorporated by reference to Exhibit 4.3 to the Annual Report on Form 10-K (File No. 001-37463) filed on March 1, 2021).
10.1+	Form of Director and Executive Officer Indemnification Agreement (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q (File No. 333-37463) filed on August 5, 2021).
10.2+	2011 Stock Plan (incorporated by reference to Exhibit 10.12 to the Registration Statement on Form S-1 (File No. 333-204091) filed on May 12, 2015).
10.3+	Form of Notice of Incentive Stock Option Grant and Stock Option Agreement under the 2011 Stock Plan (incorporated by reference to Exhibit 10.13 to the Registration Statement on Form S-1 (File No. 333-204091) filed on May 12, 2015).
10.4+	Form of Notice of Non-Statutory Stock Option Grant and Stock Option Agreement under the 2011 Stock Plan (incorporated by reference to Exhibit 10.14 to the Registration Statement on Form S-1 (File No. 333-204091) filed on May 12, 2015).
10.5+	Form of Notice of Grant of Restricted Stock Units and Restricted Stock Unit Agreement under the 2015 Omnibus Incentive Compensation Plan (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q (File No. 001-37463) filed on August 7, 2017).
10.6+	Form of Notice of Grant of Option and Option Award Agreement under the 2015 Omnibus Incentive Compensation Plan (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q (File No. 001-37463) filed on May 9, 2018).
10.7+	Form of Notice of Grant of Restricted Stock Units and Restricted Stock Unit Agreement under the 2015 Omnibus Incentive Compensation Plan (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q (File No. 001-37463) filed on August 6, 2018).
10.8+	Form of Director Notice of Grant of Restricted Stock Units and Restricted Stock Unit Agreement under the 2015 Omnibus Incentive Compensation Plan. (incorporated by reference to Exhibit 10.22 to the Annual Report on Form 10-K (File No. 001-37463) filed on February 28, 2018).
10.9+	Form of Notice of Grant of Performance-Based Equity Award under the 2015 Omnibus Incentive Compensation Plan (incorporated by reference to Exhibit 10.15 to the Annual Report on Form 10-K (File No. 001-37463) filed on March 2, 2020).
10.10+	2015 Omnibus Incentive Compensation Plan (incorporated by reference to Exhibit 10.15 to Amendment No. 2 to the Registration Statement on Form S-1 (File No. 333-204091) filed on June 15, 2015).
10.11+	2015 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.16 to Amendment No. 2 to the Registration Statement on Form S-1 (File No. 333-204091) filed on June 15, 2015).
10.12+	Thomas W. Burns Offer Letter dated July 10, 2014 (incorporated by reference to Exhibit 10.17 to the Registration Statement on Form S-1 (File No. 333-204091) filed on May 12, 2015).



<b>Exhibit Number</b>	<b>Description</b>
10.13+	Thomas W. Burns Amended and Restated Executive Severance and Change in Control Agreement dated November 3, 2017 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K (File No. 001-37463) filed on November 7, 2017).
10.14+	Joseph E. Gilliam Offer Letter dated February 3, 2017 (incorporated by reference to Exhibit 99.2 to the to the Company's Current Report on Form 8-K (File No. 001-37463) filed on February 6, 2017).
10.15+	Joseph E. Gilliam Amended and Restated Executive Severance and Change in Control Agreement dated November 3, 2017 (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K (File No. 001-37463) filed on November 7, 2017).
10.16+	Alex R. Thurman Executive Severance and Change in Control Agreement dated April 1, 2022 (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q (File No. 001-37463) filed on May 5, 2022).
10.17+	Tomas Navratil Executive Severance and Change in Control Agreement dated April 1, 2022 (incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q (File No. 001-37463) filed on May 5, 2022).
10.18+	The Executive Nonqualified Excess Plan and the Executive Nonqualified Excess Plan Adoption Agreement (incorporated by reference to Exhibit 10.20 to the Annual Report on Form 10-K (File No. 001-37463) filed on March 15, 2017).
10.19+*	Directors' Compensation Policy
10.20	Standard Industrial/Commercial Single-Tenant Lease—Net, dated as of June 8, 2015, by and between the Registrant and 229 Fabricante, LLC (incorporated by reference to Exhibit 10.35 to Amendment No. 2 to the Registration Statement on Form S-1 (File No. 333-204091) filed on June 15, 2015).
10.21	First Amendment to Lease dated as of December 31, 2018 between the Registrant and 229 Avenida Fabricante, LLC (incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q (File No. 001-37463) filed on August 7, 2020).
10.22	Second Amendment to Lease dated as of July 2, 2020 between the Registrant and 229 Avenida Fabricante, LLC (incorporated by reference to Exhibit 10.4 to the Quarterly Report on Form 10-Q (File No. 001-37463) filed on August 7, 2020).
10.23	Office Building Lease dated as of November 14, 2018, by and between the Registrant and CIP 2014/SG, Aliso Owner LLC. (incorporated by reference to Exhibit 10.27 to the Annual Report on Form 10-K (File No. 001-37463) filed on February 28, 2019).
10.24	First Amendment to Office Building Lease dated as of December 12, 2018 between the Registrant and CIP 2014/SG Aliso Owner, LLC (incorporated by reference to Exhibit 10.5 to the Quarterly Report on Form 10-Q (File No. 001-37463) filed on August 7, 2020).
10.25	Second Amendment to Office Building Lease dated as of May 20, 2020 between the Registrant and CIP 2014/SG Aliso Owner, LLC (incorporated by reference to Exhibit 10.6 to the Quarterly Report on Form 10-Q (File No. 001-37463) filed on August 7, 2020).
10.26	Amended and Restated Patent License Agreement, by and between the Registrant and DOSE Medical Corporation, dated as of June 30, 2015 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K (File No. 001-37463) filed on June 30, 2015).
10.27	First Amendment to Amended and Restated Patent License Agreement dated as of April 12, 2017 by and between Glaukos Corporation and DOSE Medical Corporation (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K (File No. 001-37463) filed on April 12, 2017).
10.28	Agreement and Plan of Merger, dated as of June 19, 2019, by and between Glaukos Corporation, GKOS Merger Sub, Inc., DOSE Medical Corporation and Fortis Advisors LLC, solely in its capacity as the Stockholders' Representative (incorporated by reference to Exhibit 99.2 to the Current Report on Form 8-K (File No. 001-37463) filed on June 19, 2019).

<b>Exhibit Number</b>	<b>Description</b>
10.29	Form of Capped Call Confirmation (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K (File No. 001-37463) filed on June 12, 2020).
21*	Subsidiaries of Glaukos Corporation as of December 31, 2022
23.1*	Consent of Independent Registered Public Accounting Firm
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2**	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH*	XBRL Taxonomy Schema Linkbase Document
101.CAL*	XBRL Taxonomy Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Definition Linkbase Document
101.LAB*	XBRL Taxonomy Labels Linkbase Document
101.PRE*	XBRL Taxonomy Presentation Linkbase Document
104	Cover Page Interactive Data File - the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document

+ Indicates a management contract or compensatory plan or arrangement.

\* Filed Herewith.

\*\* Furnished Herewith.

## **ITEM 16. FORM 10-K SUMMARY**

None.

## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of San Clemente, State of California, on February 24, 2023.

### GLAUKOS CORPORATION

By: /s/ THOMAS W. BURNS

Thomas W. Burns

Chairman & Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ THOMAS W. BURNS</u> Thomas W. Burns	Chief Executive Officer and Chairman of the Board (Principal Executive Officer)	February 24, 2023
<u>/s/ ALEX R. THURMAN</u> Alex R. Thurman	Senior Vice President & Chief Financial Officer (Principal Accounting and Financial Officer)	February 24, 2023
<u>/s/ MARK J. FOLEY</u> Mark J. Foley	Lead Independent Director	February 24, 2023
<u>/s/ DAVID F. HOFFMEISTER</u> David F. Hoffmeister	Director	February 24, 2023
<u>/s/ GILBERT H. KLIMAN</u> Gilbert H. Kliman, M.D.	Director	February 24, 2023
<u>/s/ MARC A. STAPLEY</u> Marc A. Stapley	Director	February 24, 2023
<u>/s/ AIMEE S. WEISNER</u> Aimee S. Weisner	Director	February 24, 2023
<u>/s/ LEANA S. WEN</u> Leana S. Wen, M.D.	Director	February 24, 2023
<u>/s/ DENICE M. TORRES</u> Denice M. Torres	Director	February 24, 2023

## **BOARD OF DIRECTORS**

**Thomas W. Burns**  
Chairman

**Mark J. Foley**  
Lead Independent Director  
Chief Executive Officer of  
Revance Therapeutics, Inc.

**David F. Hoffmeister**  
Former Senior Vice  
President and Chief  
Financial Officer of Life  
Technologies Corporation

**Gilbert K. Kliman, MD**  
Managing Partner of  
InterWest Partners

**Marc A. Stapley**  
Chief Executive Officer of  
Veracyte, Inc.

**Denice M. Torres**  
Chief Executive Officer of  
The Ignited Company

**Aimee S. Weisner**  
Former Corporate Vice  
President and General  
Counsel of Edwards  
Lifesciences Corporation

**Leana S. Wen, MD**  
Emergency Physician and  
Professor of Health Policy  
and Management, George  
Washington University  
School of Public Health

## **EXECUTIVE OFFICERS**

**Thomas W. Burns**  
Chairman and Chief  
Executive Officer

**Joseph E. Gilliam**  
President and Chief  
Operating Officer

**Alex R. Thurman**  
Senior Vice President and  
Chief Financial Officer

**Tomas Navratil**  
Chief Development Officer

## **CORPORATE HEADQUARTERS**

One Glaukos Way  
Aliso Viejo, CA 92656

## **INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Ernst & Young LLP  
One Manhattan West  
401 9<sup>th</sup> Ave.  
New York, NY 10001

## **TRANSFER AGENT**

American Stock Transfer  
& Trust Co LLC  
6201 15th Ave.  
Brooklyn, NY 11219  
[www.astfinancial.com](http://www.astfinancial.com)

## **GLAUKOS INVESTOR RELATIONS**

[investors@glaukos.com](mailto:investors@glaukos.com)



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