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, 2015

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. 001-3 7463

GLAUKOS CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**33-0945406**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
26051 Merit Circle, Suite 103 Laguna Hills, California (Address of principal executive office)	**92653** (Zip Code)

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

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

Common Stock, $0.001 par value per share	**New York Stock Exchange**
(Title of each class)	(Name of each exchange on which registered)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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

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

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, 2015, 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 $523.2 million. Shares of common stock held by each executive officer, director and by each person who owns 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. The determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of the Registrant's common stock outstanding as of March 7 , 2016 (latest practicable date) was 32,340,033 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement for the 2016 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 of the registrant's fiscal year ended December 31, 2015.

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We use *Glaukos* , our logo, *iStent* , *iStent Inject* , *iStent Supra* , *iDose* , *MIGS* 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 "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, and Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act). These statements are based on management's beliefs and assumptions and on information currently available to management. Some of the statements 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. 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.

These 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. Although we believe that we have a reasonable basis for each forward -looking statement contained in this report, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain.

In addition, you should refer to the "Risk Factors" section of this report for a discussion of other important factors that may cause actual results to differ materially from those expressed or implied by the forward - looking statements. As a result of these factors, we cannot assure you that the forward -looking statements in this report will prove to be accurate. Furthermore, if the forward -looking statements prove to be inaccurate, the inaccuracy may be material. 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 in any specified time frame, or at all. 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, w e have not independently verified any of the third party information. Statements in this Annual Report on Form 10-K regarding our market position, market opportunity , market size and our general expectations involve risks and uncertainties and are subject to change based on various factors, including those discussed under Item 1A - "Risk Factors" and Item 7 - "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Annual Report on Form 10-K.

PART I

ITEM 1. BUSINESS

Overview

We are an ophthalmic medical technology company focused on the development and commercialization of breakthrough products and procedures designed to transform the treatment of glaucoma, one of the world's leading causes of blindness. We have pioneered Micro ‑Invasive Glaucoma Surgery (MIGS) to revolutionize the traditional glaucoma treatment and management paradigm. We launched the *iStent* , our first MIGS device, in the United States in July 2012 and we are leveraging our platform technology to build a comprehensive and proprietary portfolio of micro ‑scale injectable therapies designed to address the complete range of glaucoma disease states and progression. We believe the *iStent* is the smallest medical device ever approved by the Food and Drug Administration (FDA), measuring 1.0 mm long and 0.33 mm wide.

Glaucoma is a group of eye diseases characterized by progressive, irreversible and largely asymptomatic vision loss caused by optic nerve damage, which is most commonly associated with elevated levels of pressure within the eye, or intraocular pressure. Elevated intraocular pressure often occurs when aqueous humor, the thin watery fluid that fills the front part of the eye, is not circulating normally and draining properly. According to Market Scope, more than 80 million people worldwide have glaucoma, a number it expects to grow to more than 90 million by 2020. This estimate includes approximately 4.3 million people with glaucoma in the United States, growing to approximately 4.8 million by 2020. Glaucoma is a chronic condition that progresses slowly over long periods of time and can have a devastating impact on a patient's vision and quality of life.

Reducing intraocular pressure is the only proven treatment for glaucoma. Glaucoma has traditionally been treated through a range of approaches that often require patients to use multiple types of prescription eye drops for the rest of their lives, and sometimes undergo complex and invasive eye surgery. Prescription eye drops, which are estimated to account for approximately $4.7 billion in global sales in 2015, according to Market Scope, are often used to control intraocular pressure throughout glaucoma progression. Unfortunately, these medications can be ineffective over time due to patient noncompliance and other factors. Complex and invasive glaucoma surgical options are typically reserved for more advanced disease and have remained largely unchanged since the 1970's.

We developed MIGS to address the shortcomings of current glaucoma treatment options. MIGS procedures involve the insertion of a micro ‑scale device from within the eye's anterior chamber through a small corneal incision. MIGS devices reduce intraocular pressure by restoring the natural outflow pathways for aqueous humor. Based on clinical studies and published reports, we believe MIGS procedures are safer, preserve more eye tissue and result in faster recovery times and fewer complications than invasive glaucoma surgical options.

The *iStent* is the first commercially available MIGS treatment solution. FDA ‑approved for insertion in combination with cataract surgery, the *iStent* has been shown to lower intraocular pressure in adult patients with mild ‑to ‑moderate open ‑angle glaucoma, which represents the majority of glaucoma cases. The *iStent* procedure is currently reimbursed by Medicare and a majority of commercial payors and we have sold more than 1 4 0,000 *iStent* devices worldwide.

We are building a broad portfolio of micro ‑scale injectable therapies designed to address the complete range of glaucoma disease states and progression, including three innovative pipeline products: the *iStent Inject* , the *iStent Supra* and *iDose* . The *iStent Inject* includes two stents pre ‑loaded in an auto ‑injection inserter. We are developing two versions of this product: the first is currently being studied for lowering intraocular pressure in conjunction with cataract surgery in a U.S. investigational device exemption (IDE) pivotal trial; the second is currently being studied in an initial U.S. IDE study as a standalone treatment for lowering intraocular pressure. This second version is also capable of making its own self ‑sealing corneal penetration, potentially offering patient treatment in a minor surgical suite or an in ‑office setting. The *iStent Supra* is designed to access an alternative drainage space within the eye where we estimate 20% of aqueous humor outflow occurs, and is now in a U.S. pivotal IDE trial. *iDose* is an implant that is designed to continuously deliver therapeutic levels of medication from within the eye for extended periods of time to lower intraocular pressure in glaucoma patients. To validate the safety and efficacy of our *iStent* products, we are currently conducting 17 prospective clinical trials.

Our corporate headquarters and production facilities are located in Laguna Hills, California, and as of December 31, 2015, we had 182 employees. We have built and are continuing to grow our commercial organization, which includes a direct sales force in the United States, Germany, Australia and Canada, and distribution partners in Europe, Asia Pacific and other targeted international geographies. Information about geog raphic revenue is set forth in Note 1 3 of our notes to consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K .

Our net sales increased to $71.7 million in 2015 from $45.6 million in 2014 and $20.9 million in 2013 , and our net losses were $38.3 million , $14.1 million and $14.2 million for the years ended December 31, 2015 , 2014 and 2013 , respectively.

Our Market Opportunity

According to Market Scope, more than 80 million people worldwide have glaucoma, a number it expects to grow to more than 90 million by 2020. This estimate includes approximately 4.3 million people with glaucoma in the United States, growing to approximately 4.8 million by 2020. Market Scope estimates 2015 global sales of products used to treat glaucoma patients to be approximately $5.1 billion, growing to approximately $7.1 billion in 2020. Open -angle glaucoma is the most common form of the disease. Approximately 3.5 million people in the United States have open -angle glaucoma, growing to approximately 3.8 million by 2020 according to Market Scope. Despite therapeutic options that attempt to manage disease progression, researchers estimate that 8.4 million people were bilaterally blind from glaucoma in 2010, with this figure forecasted to rise to 11.1 million by 2020.

Many factors are driving significant growth in the glaucoma market. Populations worldwide in both mature and emerging markets are growing and aging, while life expectancies continue to rise. Treatment of glaucoma is expected to increase due to better healthcare access globally and advances in glaucoma technology designed to provide earlier diagnosis and more cost -effective treatment to a larger portion of the glaucoma population.

Care for glaucoma patients in the United States is administered by many of the approximately 18,900 ophthalmologists who diagnose the disease and provide medical management according to Market Scope. There are more than 8,000 ophthalmic surgeons in the United States focused on performing cataract or glaucoma procedures. These ophthalmic surgeons perform approximately 3.8 million cataract surgeries annually in the United States according to Market Scope. We believe that approximately 20% of cataract surgeries are performed on patients also diagnosed with open -angle glaucoma and/or ocular hypertension. Appropriate treatment options are determined based on the progression and severity of the disease and include medical management with prescription pharmaceuticals, laser therapy, surgical therapy and now MIGS.

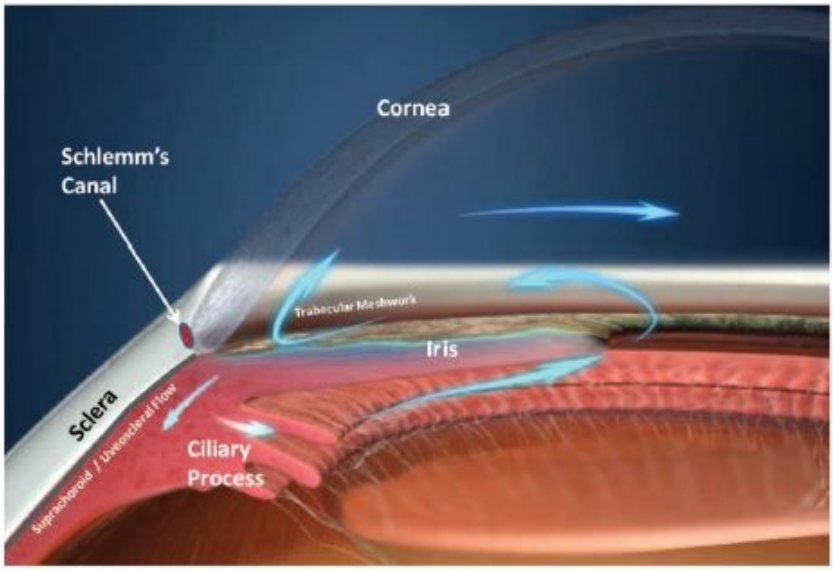
Glaucoma Treatment Overview and Limitations

Glaucoma and the eye's drainage system

Glaucoma is a group of eye diseases characterized by progressive, irreversible and largely asymptomatic vision loss in which elevated levels of intraocular pressure are often associated with optic nerve damage. While some glaucoma patients do not experience an increase in intraocular pressure, it is widely considered a major risk factor in glaucoma's progression and reduction in intraocular pressure is the only clinically proven treatment. Elevated intraocular pressure occurs when aqueous humor is not circulating normally and properly drained from the front part of the eye. Normally, this fluid flows through the trabecular meshwork, an area of spongy mesh -like tissue in the eye located around the base of the cornea, and into Schlemm's canal, a circular channel in the eye that collects the aqueous humor and delivers it back into the bloodstream. This trabecular meshwork pathway is also known as the conventional outflow pathway.

A second outflow pathway is located in the suprachoroidal space, which lies between the sclera and the choroid, where we estimate 20% of the eye's total aqueous humor outflow occurs. This pathway is also known as the unconventional or uveoscleral pathway. The suprachoroidal space is characterized as an area of less venous resistance to aqueous humor outflow than Schlemm's canal.

The following image depicts the blockage of aqueous humor outflow in an eye with open -angle glaucoma.



Open -angle glaucoma is the most common type of glaucoma. In open -angle glaucoma, structures of the eye may appear normal, but aqueous humor outflow through the trabecular meshwork and into Schlemm's canal is reduced due to gradual degeneration and obstruction. Direct causes of this blockage are unknown, but the disease is linked to age, ethnicity and hereditary factors. Loss of aqueous humor absorption leads to increased resistance and thus a chronic, painless buildup of pressure in the eye.

Glaucoma is a progressive disease that can be categorized based by severity levels ranging from ocular hypertension (or pre -glaucoma) to severe glaucoma, as shown in the chart below. According to industry experts, mild -to -moderate glaucoma patients account for a majority of the population. An eye doctor usually diagnoses glaucoma as part of a comprehensive exam that includes measuring intraocular pressure and corneal thickness, evaluating optic nerve damage and testing visual fields. Intraocular pressure is measured in millimeters of mercury (mm Hg), with normal eye pressures ranging from 10 to 21 mm Hg. Glaucoma is typically characterized by an intraocular pressure greater than 21 mm Hg.

An eye doctor will monitor optic nerve damage by tracking the cup to disc (C:D), ratio. This exam measures the diameter of the optic disc (the round area in back of the eye where retinal nerve fiber layers collect to form the optic nerve) relative to the diameter of the optic cup (the center of the optic disc). Expansion and deepening of this optic cup indicates damage. Visual field, or perimetry, tests are used to check for peripheral vision impairment in one or more

quadrants. Once diagnosed, the treatment goal in all cases is to control intraocular pressure. Glaucoma progression stages are described in the following chart.

Stage	Intraocular pressure	Optic nerve damage	Visual field	Intraocular pressure treatment target
Ocular Hypertension	20 - 30 mm Hg	No measurable or observable change	Visual function intact	20% reduction in baseline: ≤ 18 mm Hg
Mild Glaucoma	20 - 35 mm Hg	Minor; C:D ≤ 0.8 with documented expansion and deepening of cup	Some visual field loss	25% reduction in baseline; ≤ 18 mm Hg
Moderate Glaucoma	> 30 mm Hg	Significant; C:D ≤ 0.8 with documented expansion and deepening of cup	Expanded visual field loss in up to two quadrants; peripheral progressing to central loss	30% reduction in baseline; ≤ 15 mm Hg
Severe Glaucoma	Intraocular pressure uncontrolled	Severe; C:D > 0.8 with severe expansion and deepening of cup	Significant visual field loss in up to three quadrants; central loss	< 15 mm Hg

Glaucoma treatment overview

The traditional treatment of glaucoma encompasses a variety of medication regimens, laser and surgical methods to lower intraocular pressure.

Therapy	Medications	Laser	Surgery
Product or procedure	Prescription eye drops	Selective argon and micropulse lasers	Invasive trabeculectomy with or without aqueous shunt device
Treatment	First -line	First or second -line	Last resort
Description	Eye drops taken one or more times a day in single or multiple medication regimens	Laser trabeculoplasty performed at outpatient centers	Filtration surgery or aqueous shunt, a flexible plastic tube with an attached silicone drainage pouch
Mechanism of action	Increasing aqueous humor outflow and/or decreasing production of aqueous humor	SLT laser energy targets melanin -containing cells in the trabecular meshwork, creating changes in the tissue and improving the aqueous humor outflow	Creating a drainage channel from the anterior chamber and through the sclera to allow aqueous humor outflow to area beneath the conjunctiva
Considerations	Poor patient compliance; complex, frequent and lifelong dosing regimens; loss of effect over time; cost; side effects; contraindications and adverse interactions with other medications	Effects of surgery dissipate after several years necessitating additional procedures; medication therapy may be necessary post -treatment	Little innovation; high failure rates; complication risks; lack of long -term efficacy; medication therapy may be necessary post -treatment

Multiple clinical trials have shown that medications can reduce intraocular pressures to baseline targets that can minimize vision loss. However, poor adherence to and lack of persistence with glaucoma medication regimens have been documented in numerous independent studies, which often place the incidence of patient noncompliance up to or above 50%, particularly in patients on two or more prescription eye drops. Even daily glaucoma single medication use has been associated with noncompliance rates as high as 75%.

According to Market Scope, more than 47% of patients use two or more prescription eye drops. Furthermore, because glaucoma progresses slowly and with few symptoms, patients often do not adhere to their medication regimens as prescribed until the disease has progressed to the point of significant vision loss. As a result, despite the availability of medication therapies to combat glaucoma, progressive visual loss and blindness still occur. According to a study published in 2014, 15% of glaucoma patients progress to blindness within 20 years of diagnosis.

Laser treatments have been developed to provide an alternative to lifelong medication treatments. Laser procedures are typically performed at an outpatient surgical center and involve the use of lasers to create changes in eye tissue and improve aqueous humor outflow. Ophthalmic surgeons may perform laser procedures as initial treatment, or for patients who are noncompliant with prescription eye drops or whose intraocular pressure is not well controlled by medications. According to Market Scope, selective laser trabeculoplasty (SLT) is the most frequently performed glaucoma laser procedure in the United States. Although SLT can help to lower intraocular pressure, the procedure’s effectiveness often wears off within one to five years, according to the Glaucoma Research Foundation. While a second procedure can be performed, the results of repeated laser surgeries are less predictable and less effective than those of the first surgery. Additionally, medication therapy may still be required post -treatment.

Where medication therapy and laser treatment are unsuccessful in managing glaucoma, invasive surgical procedures such as trabeculectomies or implantation of tube shunts are performed, usually as outpatient procedures. In a

trabeculectomy, the surgeon cuts open the conjunctiva and sclera to create flaps, and removes a plug of scleral tissue and sometimes a portion of the trabecular meshwork to create an opening into the anterior chamber. The conjunctiva and sclera flaps are sutured back down and a small blister, or bleb, is created between the conjunctiva and sclera. The surgery results in a new drainage channel that allows increased outflow of aqueous humor into the bleb. While some patients experience significant reductions in intraocular pressure, trabeculectomy failure rates can approach 50% according to published research. A common complication is scarring, which can prevent fluid drainage from the eye and interfere with the proper function of the bleb. If the bleb doesn't work properly, more surgery may be needed. Among the other complications associated with trabeculectomies are blurred vision, bleeding in the eye, bleb leaks, low intraocular pressure, or hypotony, infection, persistent corneal edema, choroidal detachment and cataract development. Implantations of tube shunts, devices that divert the aqueous humor from the anterior chamber, are generally reserved for eyes in which a trabeculectomy has failed or has a poor likelihood of success. A tube shunt surgery is similar to a trabeculectomy, except that the device's tube is inserted through the scleral channel to maintain the channel, and the device's reservoir end is placed deep under the conjunctiva to maintain the drainage space. While invasive glaucoma surgery often leads to significant reductions in intraocular pressure, it is associated with high long ‑term failure rates, long recovery times and significant complication risks. Additionally, as with laser treatment, the effects may dissipate over time, requiring additional procedures, and medication therapy may still be required post ‑treatment.

We believe that because of the limitations of medications and laser and the morbidity associated with invasive surgical therapies, a clear unmet medical need exists in the management of open ‑angle glaucoma patients.

Our Solution

We pioneered the development of MIGS in order to address the shortcomings of current pharmaceutical and surgical options, and in doing so have established an entirely new market segment within the global glaucoma marketplace. We believe that by using our core competencies to develop, manufacture and obtain regulatory approval for products incorporating our proprietary technologies, we have created a platform capable of disrupting and revolutionizing the traditional glaucoma treatment and management paradigm.

In contrast to invasive surgical approaches, MIGS procedures access the anterior chamber of the eye through small corneal incisions or penetrations. MIGS procedures reduce intraocular pressure by restoring the natural physiologic pathways for aqueous humor outflow. Based on clinical studies and published reports, we believe MIGS procedures are safer, preserve more eye tissue and result in faster recovery times and fewer complications than invasive glaucoma surgical options.

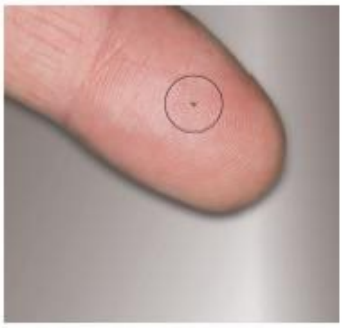
We launched our first micro ‑scale MIGS treatment solution, the *iStent* , in the United States following FDA approval in June 2012. We believe the *iStent* represents the next generation in glaucoma surgical innovation and it is the first FDA ‑approved surgical device available for insertion in conjunction with cataract surgery for the reduction of intraocular pressure in adult patients with mild ‑to ‑moderate open ‑angle glaucoma. The *iStent* is a micro ‑bypass stent made of surgical ‑grade non ‑ferromagnetic titanium that is coated with heparin. An extensive history of development efforts preceded the current form of the *iStent* , with contribution by our Caltech ‑associated founder, during which more than 80 prototype iterations were produced. Packaged in a sterile, pre ‑loaded configuration, the *iStent* is inserted through the small corneal incision made during cataract surgery and placed into Schlemm's canal, a circular channel in the eye that collects aqueous humor and delivers it back into the bloodstream. Once inserted, the *iStent* improves aqueous humor outflow while fitting naturally within Schlemm's canal. The ergonomic rail design protects and accesses underlying collector channels while the *iStent* 's three retention arches ensure secure placement. The *iStent* is currently approved only for insertion in conjunction with cataract surgery because this was the product usage in the U.S. IDE clinical trial information that was included in the premarket approval (PMA).

The *iStent* is rated "MRI Conditional" by the American Society for Testing and Materials. This means that a patient implanted with the *iStent* can be scanned safely via magnetic resonance imaging (MRI) under the following conditions specified on the product label: static magnetic field of 3 ‑Tesla or less, and maximum spat ial magnetic field gradient of 4,000 ‑Gauss/cm or less. Therefore, it may not be safe for *iStent* recipients to undergo MRIs in environments that do not match these specified conditions; however, the vast majority of MRI systems in use in the United States today are rated 3 ‑Tesla or less. Following implantation of an *iStent* , the surgeon is instructed to provide to the patient a wallet ‑sized patient identification card citing the model and serial number of the device, implant date, and surgeon's

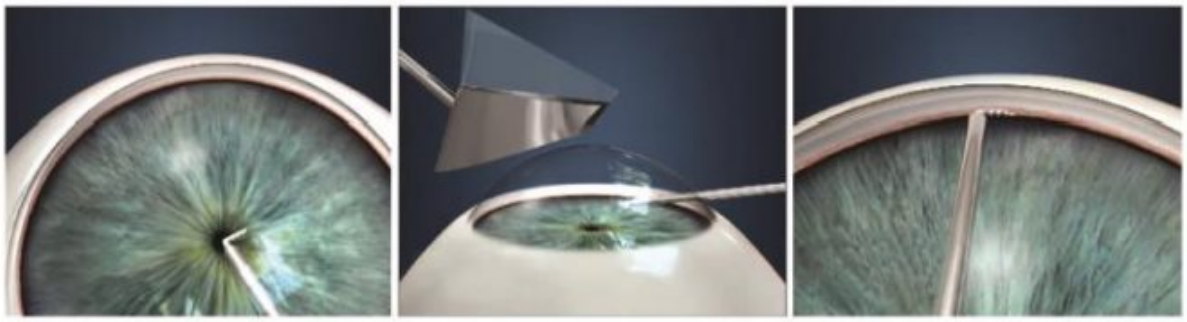
name along with the aforementioned MRI conditions. The surgeon is also instructed to advise the patient that the patient identification card contains important information related to the *iStent* and that the card should be shown to their current and future health care providers.

The image below left shows a gloved hand holding the pre -loaded *iStent* inserter; the image below center is a magnified view of the insertion tip and *iStent* device; the image below right shows an *iStent* on the tip of a finger (inside circle).

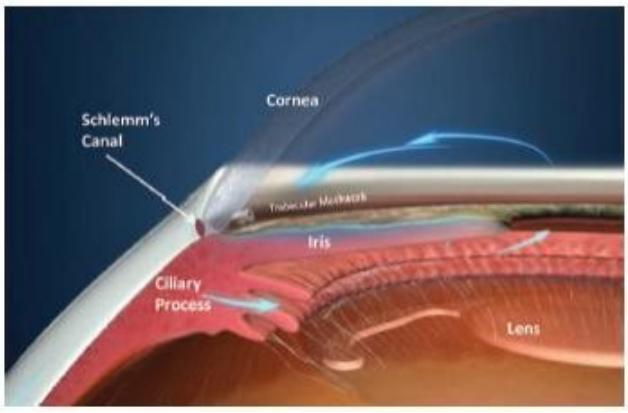


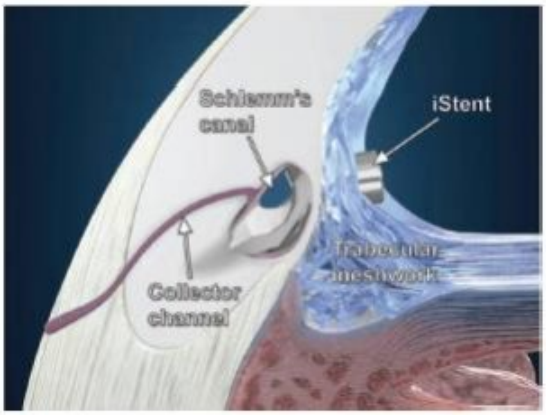


The following series of graphics illustrates the insertion of an *iStent* into the eye: (left) the pre -loaded *iStent* inserter enters the anterior chamber through a small corneal incision made during cataract surgery; (center) a gonioscope is used to visualize Schlemm's canal; (right) the *iStent* is inserted into Schlemm's canal.



The following series of graphics illustrates the effect of *iStent* in the eye: (left) after placement of the *iStent* , aqueous humor outflow is restored; (right) close ‑up illustration of *iStent* placement in Schlemm's canal.





In combination with cataract surgery, the *iStent* has been clinically proven to decrease intraocular pressure. We believe the *iStent* provides numerous benefits that address the significant unmet need for a durable and effective glaucoma treatment earlier in the treatment paradigm. These benefits include:

Reduces intraocular pressure. In the pivotal U.S. clinical trial, after one year, 68% of mild ‑to ‑moderate open ‑angle glaucoma patients who received the *iStent* in combination with cataract surgery remained medication free while sustaining target intraocular pressures of ≤ 21 mm Hg, a level consistent with normal, non ‑glaucomatous eyes. In the same trial, 64% of patients who received the *iStent* remained medication free while sustaining a mean intraocular pressure reduction of 20% compared to baseline.

Facilitates compliance, convenience. The *iStent* is designed to establish continuous outflow of aqueous fluid for sustained reduction in intraocular pressure. This mechanism is intended to assure uninterrupted therapy, thus overcoming the primary limitation of patient noncompliance to prescribed eye drop regimens. By reducing intraocular pressure on a sustained basis, *iStent* efficacy does not depend on patients remembering to use their prescription eye drops. Re ‑establishing normal, steady ‑state physiologic outflow of aqueous humor may reduce the large fluctuations in intraocular pressure that occur throughout the day in glaucoma patients. These large fluctuations in intraocular pressure have been shown in independent studies to be a significant risk factor in glaucoma progression.

Safe procedure and rapid recovery. Clinical studies have demonstrated that inserting the *iStent* in combination with cataract surgery yields an overall safety profile and recovery rate similar to cataract surgery alone, a surgery that has minimal complications and is the most commonly performed ophthalmic procedure today. The *iStent* procedure is not associated with the complication risks of invasive glaucoma surgery, and it also spares conjunctival tissue, or the clear skin that covers the sclera, enabling rapid recovery and preserving the potential for future glaucoma treatment options.

Broad segment of ophthalmic practitioners can perform procedure. Because the *iStent* procedure is straightforward, a broad segment of ophthalmic surgeons can effectively perform the MIGS procedure to insert an *iStent* . We believe this characteristic increases the procedure's appeal and utilization as an early and effective treatment option for ophthalmic surgeons.

Our Pipeline

Our research and development goal is to leverage our core capabilities in MIGS ‑based design and development to create a full portfolio of micro ‑scale injectable therapies for glaucoma management. We have developed a series of innovative products, in varying stages of development, that are designed to expand market penetration and adoption,

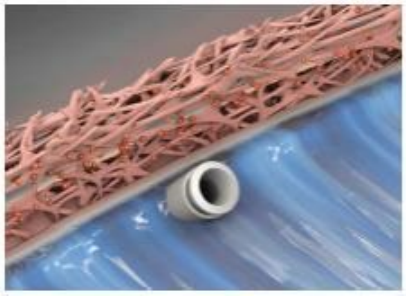
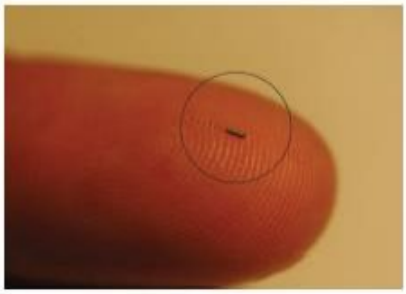
further enhance ease of use for surgeons, reach a wider glaucoma patient population and broaden our offering for glaucoma management in order to address the complete range of glaucoma disease states and progression:

iStent Inject trabecular micro-bypass stent. The *iStent Inject* is approximately one-third the size of the *iStent* and relies on a similar method of action to improve aqueous humor outflow into Schlemm's canal and reduce intraocular pressure. Packaged in a two-stent, preloaded, auto-inject mechanism, the *iStent Inject* allows the surgeon to inject these stents into multiple trabecular meshwork locations through a single corneal entry with the goal of achieving greater intraocular pressure reduction. We are developing two versions of this product. One version of the *iStent Inject* is currently being evaluated in a pivotal U.S. IDE clinical trial for the reduction of intraocular pressure in mild-to-moderate open-angle glaucoma in combination with cataract surgery. A second version of the *iStent Inject* is designed to make its own self-sealing corneal needle penetration to achieve insertion without an incision. A n initial U.S. IDE study i s currently underway to evaluate this second version of the device as a stand-alone procedure in glaucoma patients who are not undergoing concurrent cataract surgery. Both versions of the *iStent Inject* have been approved for marketing in the European Union and Canada and are currently in a commercial launch in Germany and Canada. The version of the *iStent Inject* that may be used for the reduction of intraocular pressure in mild-to-moderate open angle glaucoma in combination with cataract surgery is approved for marketing and currently in a commercial launch in Australia.

The image below left is the *iStent Inject* injection system, pre-loaded with two *iStent Inject* devices; the image below center is a magnified view of two *iStent Inject* devices; the image below right shows two *iStent Inject* devices on a penny (inside circle).

iStent Supra suprachoroidal micro-bypass stent. The *iStent Supra* is designed to reduce intraocular pressure by accessing the suprachoroidal space in the eye, an area that we estimate is responsible for 20% of its total aqueous outflow. We believe that the *iStent Supra* device could be used alone to lower intraocular pressure or in combination with the *iStent* or the *iStent Inject* to achieve even lower intraocular pressure in patients with progressive or more advanced open-angle glaucoma. An international study showed the *iStent Supra* achieved a 30% pressure reduction in comparison to the unmedicated baseline at 12 months. A U.S. pivotal IDE trial for the *iStent Supra* used in conjunction with cataract surgery to lower intraocular pressure is underway. The *iStent Supra* device has already been approved for marketing in the European Union.

The image below left is a magnified view of the *iStent Supra* ; the image below center illustrates the *iStent Supra* device implanted into the suprachoroidal space of the eye; the image below right shows the *iStent Supra* device on the tip of a finger (inside circle).

iDose. The *iDose* is a targeted injectable drug delivery implant that uses our micro -scale platform. The *iDose* implant is designed to be pre -loaded into a small gauge needle and injected into the eye via a self -sealing corneal needle penetration, where it is secured within the eye. Once secured in the eye, the *iDose* is designed to continuously deliver therapeutic levels of medication from within the eye for extended periods of time. The titanium implant is comparable in size to the Company's other proprietary MIGS devices. It is filled with a special formulation of travoprost, a prostaglandin analog used to reduce elevated intraocular pressure. The implant is capped with a membrane that is designed for continuous controlled drug elution into the anterior chamber. When depleted, the implant can be removed and replaced in a similar, subsequent procedure. Glaukos has designed the product to be an alternative to chronic, daily prescription eye drop treatments, which may have high rates of patient noncompliance and cause long -term ocular surface damage to glaucomatous eyes. In November 2015, the Company submitted an Investigational New Drug (IND) application to the FDA seeking authorization to study the *iDose* delivery system for investigational use in the reduction of elevated intraocular pressure in patients with glaucoma. In the IND application, we proposed to conduct a randomized and 12- week masked Phase II clinical trial to assess the safety and preliminary efficacy of two models of the *iDose* delivery system with different travoprost elution rates compared to topical timolol maleate ophthalmic solution, 0.5%. In addition, the IND application included information on travoprost's history of safety and efficacy, as well as Glaukos' preclinical program and early data from an initial international clinical trial on the *iDose* implant involving 69 patients. In this initial international study, subjects were randomized to receive either one of two models of the implant, each with different elution rates, or topical travoprost. Through 12 months, mean intraocular pressure was lower in the implant groups than in the topical medication group. The results from this initial trial demonstrated that both implant models had a potent intraocular pressure -lowering effect and that the implants were generally well -tolerated. In December 2015, the FDA allowed the Phase II clinical trial of *iDose* to proceed. We plan to initiate the Phase II clinical trial for *iDose* in early 2016.

Our injectable therapies could further transform the glaucoma patient value proposition. We believe newly diagnosed glaucoma patients, and mild -to -moderate open -angle glaucoma patients who have failed on medication therapy, or those who are noncompliant with their prescribed eye drop regimens, could have *iStent* or *iDose* injectable therapy as a meaningful alternative to lifelong treatment with prescription eye drops. Our simple, straightforward injectable solutions may reduce the daily need, side effects and cost of prescription eye drops.

Research & Development

We are leveraging our micro -scale technology platform to address the full range of glaucoma disease states and progression and to fundamentally change the way glaucoma patients are treated. Our research and development efforts are focused primarily on continuous improvement of our *iStent* designs and injector systems and improvements to our proprietary MIGS platform. Our research and development objectives are:

- To advance glaucoma patient care through continuous improvement of the MIGS platform, to provide a viable MIGS alternative to lifelong medication regimens and invasive surgical procedures for intraocular pressure management; and

- To further transform glaucoma treatment and care by introducing micro ‑scale injectable therapies—including our *iStent Inject* , *iStent Supra* and *iDose* pipeline products—that can be performed in minor surgical suites or in ‑office settings with topical anesthetic.

As of December 31, 2015, our research and development team consisted of 66 employees. Our research and development process is supported by multiple clinical research programs and regulatory affairs activities. We currently have 17 prospective clinical trials underway. In addition, our technologies have been discussed in 40 articles published in peer ‑reviewed journals to date. Our research and development expenses were approximately $ 25.0 million , $19.2 million and $15.5 million in the years ended December 31, 2015, 2014 and 2013, respectively. We expect our research and development expenditures to increase as we continue to devote significant resources to clinical trials and regulatory approvals of our new products.

iStent clinical validation

The *iStent* pivotal U.S. clinical trial that served as the basis for the FDA approval of our PMA application by the FDA was the first prospective, randomized, open ‑label, multi ‑center, controlled U.S. IDE clinical trial ever to be conducted in support of a glaucoma device. A total of 29 U.S. investigational sites participated in the trial, which demonstrated that insertion of the *iStent* in patients undergoing cataract surgery provided clinically and statistically significant improvements in intraocular pressure and an overall safety profile similar to cataract surgery alone.

To be enrolled in the trial, subjects were required to have mild or moderate open ‑angle glaucoma with visual field or nerve pathology characteristic of glaucoma, a C:D ratio of 0.8 or less, and intraocular pressure ≤ 24 mm Hg while taking one to three prescription eye drops. After discontinuation of glaucoma medications, intraocular pressure was required to be between 22 mm Hg and 36 mm Hg. Excluded from the trial were individuals with severe glaucomatous field defects, severely uncontrolled intraocular pressure, angle closure glaucoma, neovascular, uveitic or angle recession glaucoma, prior glaucoma surgery other than iridectomy, prior refractive procedures, known corticosteroid responders, ocular disease that would affect safety, monocular subjects or those with fellow eye best corrected visual acuity, or BCVA, worse than 20/200. In this study, the “p” values were statistical calculations to determine whether the effects of receiving the *iStent* in conjunction with cataract surgery were significant in comparison to cataract surgery alone based on pre ‑specified statistical targets. We specified that any result where $p \leq .05$ would be significant.

A total of 240 eyes (239 subjects) were randomized, of which 117 were randomized to receive the *iStent* in conjunction with cataract surgery (treatment group) and 123 to cataract surgery only (control group). Of the 117 eyes randomized to the treatment group, 111 underwent insertion of the *iStent* in conjunction with cataract surgery. Of the 123 eyes randomized to receive cataract surgery only, 117 eyes underwent cataract surgery. At the 12 ‑month visit, subject accountability was 97% in the treatment group and 99% in the control group. After the randomized phase of the trial, an additional 50 subjects were enrolled for the safety purposes in the non ‑randomized phase.

Pivotal trial efficacy data

Of subjects in the treatment group, 68% achieved the primary efficacy endpoint of an intraocular pressure ≤ 21 mm Hg without prescription eye drops at 12 months, compared to 50% for the control group ($p = 0.004$). Of subjects in the treatment group, 64% achieved the secondary efficacy endpoint of intraocular pressure reduction ≥ 20% without prescription eye drops at 12 months, compared to 47% in the control group ($p = 0.010$). Throughout the postoperative period, prescription eye drops were prescribed in a lower proportion of patients, and initiated later, in the treatment group than in the control group. At 12 months, 85% of treatment group subjects were medication free compared to 65% of control group subjects at 12 months.

Pivotal trial safety data

The following table provides information on the most common adverse events reported in the pivotal trial.

Adverse events	Cataract surgery with iStent N=116 n (%)	Cataract surgery only N=117 n (%)
Early postop corneal edema	9 (8) %	11 (9) %
Any BCVA loss of at least one line at or after the three-month visit	8 (7) %	12 (10) %
Posterior capsular opacification	7 (6) %	12 (10) %
Stent obstruction	5 (4) %	0 (0) %
Blurry vision or visual disturbance	4 (3) %	8 (7) %
Elevated intraocular pressure	4 (3) %	5 (4) %

The overall rate of adverse events was similar between the treatment and control groups and no unanticipated adverse device complications were reported. The trial showed that when inserted in conjunction with cataract surgery for subjects with mild -moderate open -angle glaucoma, the benefits of the *iStent* procedure exceeded its risks.

Additional iStent studies

Two -year results from the pivotal trial showed relatively similar outcomes, although it was not designed nor statistically powered for two -year efficacy endpoints. Numerous other studies performed in Western Europe and the United States evaluating the *iStent* in combination with cataract surgery have found statistically significant reductions in mean intraocular pressure and medication use. For example, in a prospective, double -masked, randomized controlled trial on 36 patients with cataract and primary open -angle glaucoma, patients who received a single *iStent* in conjunction with cataract surgery showed an intraocular pressure decline to 14.8 mm Hg from 17.9 mm Hg at 15 months. This compared to an intraocular pressure decline to 15.7 mm Hg from 17.3 mm Hg in patients who underwent cataract surgery only. This trial included a washout of medications at 15 months in order to remove the confounding effect of glaucoma medications and, at 16 months, intraocular pressure was 16.6 mm Hg in the combined group, compared to 19.2 mm Hg in the cataract surgery -only group.

Two other Western European studies have demonstrated the sustained efficacy and safety of a single *iStent* inserted in combination with cataract surgery af ter three or more years of post operative follow up. In one international prospective, non -comparative, uncontrolled, non -randomized, interventional case series study, 19 subjects with mild -to -moderate open -angle glaucoma underwent *iStent* implantation in conjunction with cataract surgery. At a mean follow -up of 53 months, patients' mean intraocu l ar pressure was 16.3 mm Hg, compared to preoperative medicated intraocular pressure of 19.4 mm Hg. In 42% of patients, no glaucoma medications were used at the end of follow -up and the mean number of prescription eye drops used by the patients declined to 0.8 from 1.3 medications preoperatively.

The other Western European study, a prospective, open -label, non -randomized study, assessed the long -term postoperative outcomes of one *iStent* implanted during cataract surgery in subjects with primary open -angle glaucoma, pseudoexfoliation glaucoma, secondary or post -traumatic glaucoma or ocular hypertension. There was no preoperative medication washout period and 40% of eyes had undergone previous glaucoma surgeries, primarily laser procedures. In the study, a single *iStent* was implanted through the same incision used for cataract surgery in a consecutive series of 62 eyes of 43 subjects. In 39 eyes followed through three years, the mean intraocular pressure at three years was 14.9 mm Hg, compared to a mean preoperative intraocular pressure of 23.4 mm Hg, representing a 36% decline. In the same 39 eyes, the mean number of glaucoma medications used three years following surgery declined to 0.3, compared to a mean of 1.9 medications at subjects' preoperative visits, representing an 86% reduction. No operative complications occurred during the cataract surgical procedure or during the stent implantation procedure. Over the three -year follow -up period, five secondary surgeries, two postoperative ocular sequelae and two non -ocular adverse events were reported.

Additional iStent studies with multiple stents in standalone procedures

In a prospective, pilot study in Eastern Europe, 39 phakic and pseudophakic subjects with open ‑angle glaucoma and preoperative unmedicated intraocular pressure between 22 mm Hg and 38 mm Hg received two *iStents* in a standalone procedure. At 36 months, subjects not taking medication achieved mean intraocular pressure of 15.2 mm Hg, representing a 37% reduction from unmedicated baseline intraocular pressure. In four subjects who required medication, intraocular pressure ranged from 13 mm Hg to 15.7 mm Hg at 36 months. There were no postoperative adverse events related to stent implantation, except for one incidence of early postoperative hyphema that resolved at one week. The study is designed for follow ‑up through five years.

In another international prospective, randomized study, 119 subjects with open ‑angle glaucoma and preoperative unmedicated intraocular pressure between 22 mm Hg and 38 mm Hg received one, two or three *iStents* in a standalone procedure. In this study, the number of stents was based on randomization and not on each glaucoma patient's specific needs. The study design included a primary efficacy endpoint of ≥ 20% intraocular pressure reduction at 12 months from baseline unmedicated intraocular pressure without use of prescription eye drops or secondary glaucoma procedures. The secondary efficacy endpoint was intraocular pressure ≤ 18 mm Hg at 12 months without use of prescription eye drops or secondary glaucoma procedures. Approximately 89%, 90% and 92% of the one ‑, two ‑ and three ‑stent groups met the primary and secondary endpoints, respectively. In addition, at 18 months, mean unmedicated intraocular pressure was 15.9 mm Hg, 14.1 mm Hg and 12.2 mm Hg in the one ‑, two ‑ and three ‑stent groups, respectively. No intraoperative ocular adverse events occurred and safety data were similar across all stent groups. By month 18, four eyes had undergone cataract surgery due to progression of cataract. Under the study design, follow ‑up will continue through five years.

To show the benefits of combining trabecular meshwork stents and suprachoroidal stents to achieve dual physiologic outflow in patients with severe glaucoma, 80 failed trabeculectomy patients received two iStents, one iStent Supra and one prescription eye drop in an international study. In 49 patients followed through 12 months, mean intraocular pressure declined 49% to 13.4 mm Hg, compared to a baseline intraocular pressure of 26.4 mm Hg. In addition, 100% of patients met the primary endpoint of ≥ 20% reduction in intraocular pressure at 12 months.

Sales and Marketing

In the United States, we sell our products through a direct sales organization that, as of December 31, 2015, consisted of 65 sales professionals, including regional business managers, sales directors, clinical relations personnel and reimbursement specialists. Our sales organization is primarily responsible for training ophthalmic surgeons on the *iStent* procedure, helping these physicians integrate the technology into their practices and providing resources to support reimbursement, while also identifying and supporting investigational sites for clinical trials of our pipeline technologies. We continue to recruit experienced sales professionals with extensive sales and/or clinical experience in ophthalmic medical technologies. Our weighted average number of domestic sales representatives increased to 45 for the year ended December 31, 2015 from 35 for the year ended December 31, 2014. The higher number of sales representatives in each period helped increase our customer base, leading to growth in unit sales. Increased unit volume was responsible for the majority of the increase in net sales for the three months and year ended December 31, 2015.

We invest significant time and expense to provide comprehensive training to our sales professionals so that they are proficient in all aspects of our *iStent* technologies, including features and benefits, procedure techniques and reimbursement. In addition, we provide technical education regarding the eye's anatomy, glaucoma diagnosis, disease states and treatment, and cataract surgery.

Outside the United States, we sell our products primarily through a network of distribution partners located in markets where we see the greatest potential for *iStent* adoption. In late 2013, we formed a wholly ‑owned subsidiary in Germany that employs five direct sales representatives. In early 2015, we formed a wholly ‑owned subsidiary in Japan that employs five direct sales representatives. We intend for this subsidiary to commence a commercial launch in the event we receive regulatory approval to market the *iStent* in Japan. Following our initial public offering (IPO), we formed wholly ‑owned subsidiaries in Australia and Canada. In Australia, we have hired a general manager and five direct sales representatives who commenced a commercial launch in January 2016. In Canada, we have hired a general manager and five direct sales representatives who commenced a commercial launch in January 2016. We continually

monitor our international sales progress and will consider conversion to a direct sales approach on a country -by -country basis, depending on our assessment of market conditions, net sales and profitability trends, reimbursement coding and coverage potential, and other factors. As of December 31, 2015, we had agreements with approximately 1 7 distributor organizations. No single distributor accounted for more than 10% of our total net sales for the years ended December 31, 201 5 , 2014 or 201 3 .

Our global sales efforts and promotional activities are currently aimed at ophthalmic surgeons and other eye care professionals. Our primary customers include ophthalmic surgeons, hospitals and ambulatory surgery centers (ASCs). We require physicians to complete a mandatory training program before commencing *iStent* procedures. To facilitate this, we have developed a multi -faceted education program that includes interactive webinars, wet -lab training, in -office didactic sessions, observation of surgical cases and off -site information seminars. We also offer physician -to -physi cian training that involves pre operative diagnostics , procedure assistance and post operative consultations. We believe our education and training programs enable ophthalmic surgeons and other eye care professionals to improve patient outcomes and satisfaction with the *iStent* and procedure.

We support our sales organization with marketing programs and initiatives designed to build awareness and appreciation for our *iStent* technologies. These include advertisements and editorial coverage in professional publications, exhibits at major ophthalmic congresses and meetings, MIGS and *iStent* user meetings, and targeted direct -to -consumer marketing efforts.

Reimbursement

United States reimbursement

Reimbursement for iStent procedure

There are three key aspects of reimbursement in the United States:

- Coding refers to distinct numeric and alphanumeric 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.
- Coverage refers to decisions made by individual payors as to whether or not to pay for a specific procedure and related supplies and if so, under what conditions (*i.e.* , for which specific diagnoses and clinical indications). Payors typically base coverage decisions on reviews of the published medical literature.
- Payment refers to the amount paid to providers for specific procedures and supplies. Payment is generally determined for the specific billing code and, in addition, there may be separate numeric codes, under which the billing code is classified, to establish a payment amount.

In 2008, in consultation with and with the approval of the American Academy of Ophthalmology, we applied for and received a temporary Category III CPT code to describe insertion of devices such as the *iStent* using MIGS procedures.

Category III codes expire five years after the date they become effective. Prior to expiration, there are two options: submit an application to convert to a Category I code; or submit an application for a five year extension of Category III status. CPT code 0191T, which describes the insertion of the *iStent* and *iStent Inject* devices, first became effective in 2008. Prior to expiration, an application for a five - year extension was approved in 2012 and expires on December 31, 2018 . We will need to either submit an application to convert CPT code 0191T to a Category I code or apply for another five-year extension by June 2017 in order for the new code to be effective by January 1, 2019 .

We also successfully applied for, and the American Medical Association created, a new CPT code 0253T, which describes the insertion of the *iStent Supra* device, in 2011. An application for a five - year extension was approved at the same time as the application for the extension of CPT code 0191T. We will need to either submit an application for a Category I code or apply for another five -year extension by June 2017.

The *iStent* is approved by the FDA for reduction of intraocular pressure in adult patients with mild -to -moderate open -angle glaucoma undergoing cataract surgery who are currently treated with prescription eye drops. Based on data released by Centers for Medicare & Medicaid Services (CMS) regarding total cataract surgery volume in the Medicare Fee for Service program and data published by Market Scope, we estimate that Medicare pays for 70% of all cataract surgeries performed in the United States. Due primarily to strong published clinical data, including the FDA pivotal trial, all MACs had begun covering the *iStent* procedure by February 2013, approximately seven months after FDA approval.

We estimate that 20% of patients who meet the FDA indication for *iStent* insertion are covered by private health insurance companies, and we have secured positive coverage policies for *iStent* insertion with many of these private payors. As of December 31, 2015, we had secured reimbursement for the *iStent* insertion for approximately 80% of individuals covered by private insurance . These include United HealthCare, CIGNA, Aetna and all Blue Cross and Blue Shield (BCBS) plans except Anthem BCBS , Humana and Tricare . The positive coverage by most of the BCBS plans is a result of medical policy issued by the BCBS Association (national) in October 2013 stating that *iStent* insertion is considered medically necessary for mild -to -moderate open -angle glaucoma patients undergoing cataract surgery. While BCBS plans, which are independent licensees, are not required to follow BCBS national guidelines, the majority of the plans do so. We continue to work with private insurance providers in an effort to broaden coverage for the *iStent* procedure.

iStent insertion in the United States is almost always performed in an outpatient setting and virtually all U.S. *iStent* sales are to ASCs and hospital outpatient departments (HOPDs). At the average facility, 70% of claims reporting *iStent* insertion with cataract surgery will be processed and paid for by Medicare. National payment rates by Medicare to ASCs and HOPDs are determined each year through a complex formula, which takes into account reported costs for each claim submitted. When two procedures are performed in an ASC on the same patient on the same day (*e.g.* , *iStent* insertion and cataract surgery), Medicare reduces the payment of the lower -paying procedure by 50%. The ASC facility payment for cataract surgery is generally lower than the payment for *iStent* insertion. Therefore, when these two procedures are performed together in an ASC, the payment for cataract surgery is reduced by 50%. We believe that the incremental payment the ASC facility receives for performing *iStent* insertion in conjunction with cataract surgery over and above what the facility would receive for performing cataract surgery alone covers the cost of the *iStent* device and the profit for the facility. The incremental ASC facility payment has remained relatively stable over the past few years, however there is no assurance that this payment will remain stable in the future. If the incremental facility payment were to decrease such that it did not cover the cost of the *iStent* device, it could reduce the profit margin of the ASC where the cataract surgery is performed, make it difficult for existing customers to continue using, or new customers to adopt, our products and create additional pricing pressure for us.

Reimbursement for *iStent* insertion and cataract procedures performed in HOPDs was similar to ASCs until CMS implemented a rule change, effective January 1, 2016, reflecting a trend by CMS of bundling payment for procedures that are clinically similar and performed at the same time in HOPDs. Procedures covered by these combined reimbursement codes are grouped into levels and reimbursed with a single, all -inclusive payment. As a result of this recent rule change, CMS combined the cataract and MIGS/ *iStent* procedure within a single comprehensive reimbursement code, which eliminated the separate 50% facility reimbursement for the cataract portion of the procedure when performed in the HOPD. While this change will result in lower Medicare fee -for -service reimbursement when *iStent* and cataract procedures are performed at the same time in HOPDs, we do not expect it to have a material impact on our 2016 *iStent* utilization rates. We intend to preserve our current HOPD pricing on the *iStent* device. We estimate that approximately 25% of US *iStent* procedures are currently performed in HOPDs but only a portion of these procedures are reimbursed through traditional Medicare fee -for -service. This change will likely reduce the profit margin of the *iStent* and cataract procedure for some HOPD customers and could potentially make it more difficult for some existing HOPD customers to continue using, or new HOPD customers to adopt, our products and could create additional pricing pressure on the *iStent* implant.

Physicians are paid separately from the facility for surgical procedures. Unlike the facility payment, for the CPT code that describes *iStent* insertion, there is no published Medicare payment schedule at the national level, and the physician payment rate is left to the discretion of the individual Medicare contractor. In order to adopt a new procedure, one of the factors that the surgeon evaluates is whether or not payment for the procedure adequately covers the surgeon’s time. As with the facility payment, the incremental payment the physician receives for inserting the *iStent* device in conjunction with cataract surgery over and above what he or she would receive for performing cataract surgery alone

plays a role in a surgeon's decision to adopt the technology. We estimate that the national average incremental payment is approximately $500.

Unlike Medicare, commercial payors do not publish fee schedules. In general, based on selected feedback from facilities and surgeons, payments for *iStent* insertion from the commercial payors who cover the procedure generally run somewhat higher than the comparable local Medicare payment.

Reimbursement for future products

We have also filed and received approval of applications for CPT codes that describe our pipeline *iStent* devices. Our application for a CPT code to describe insertion of the *iStent Supra* was approved by the American Medical Association, or AMA, in 2011 resulting in the creation of Category III CPT code 0253T. Our application for a CPT code to describe the insertion of additional trabecular meshwork stents (as with the *iStent Inject* procedure) was approved by the AMA in early 2014 resulting in the creation of Category III CPT code 0376T. While this code was available beginning on January 1, 2015, for the reporting of procedures in which more than one *iStent* is inserted in the same eye, it currently does not result in any incremental facility or professional fee payment from Medicare. In addition, it is unclear whether any other third ‑party payor will cover the insertion of a second stent or that payment for a second stent will be adequate.

Reimbursement outside the United States

Reimbursement in Europe

In most of the developed European countries, healthcare is funded by the central government. In general, obtaining broad ‑based reimbursement and adequate payment for new technologies is more difficult in these markets than in the United States. As with the United States, high ‑quality published clinical data (*i.e.* , randomized, controlled trials) is required to obtain coverage. However, most of the developed European 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. Conversely, while some U.S. private insurers take cost into consideration, Medicare by law does not consider cost in its coverage decisions.

Our primary focus has been on the U.S. market and we are in the early stages of commercialization in Europe. With regard to reimbursement in the larger developed countries, we have made the most progress in Germany. Prior to 2013, surgeons in Germany who implanted the *iStent* used a code for a general glaucoma operation. This code was only payable in the hospital inpatient setting and, although the payment was sufficient to cover the cost of the *iStent* and payment to the surgeon, the requirement of an overnight stay in the hospital was a significant barrier to adoption. Effective January 1, 2013, there is a specific code (5 ‑133.9) describing implantation of a trabecular stent (*e.g.* , the *iStent* and *iStent Inject*). This code was added to the Einheitlicher Bewertungsmaßstab (EBM) or Unified Rating Scale of procedures that are payable in the outpatient setting. The 5 ‑133.9 code can be reported in conjunction with cataract surgery or as a stand ‑alone procedure. In addition, the payment to the surgeon for 5 ‑133.9 is considered adequate to cover the surgeon's costs (*i.e.* , time) for inserting the *iStent* . Also, under the EBM, the cost of the implant can be passed through to the payor.

Although under German law healthcare is a universal right, and approximately 90% of the population is covered under the Statutory Health Insurance (SHI) or public plan, coverage decisions and payment are decentralized. Physicians who treat SHI patients must belong to a Kassenärztliche Vereinigung (KV) or Physician's Association. There are 17 KVs in Germany, and the KVs are responsible for negotiating the budget with the State Sickness Fund for physician and facility payments for outpatient procedures in their region. Generally, procedures that are added to the EBM are covered and paid for by the KVs; however, this is not automatic and the process of achieving routine payment for a new procedure listed on the EBM can take several months. With several KVs, an application must be made to the KV by a surgeon in that area who wishes to perform the procedure. In some cases, the addition of a new outpatient procedure can create budget issues and there can be a delay while the KV negotiates additional funds with the State Sickness Fund to cover payment for the new procedure.

Surgeons in each of the states continue to work to gain KV approval so that claims are processed smoothly. While the majority of claims submitted to KVs in 2015 were processed and paid, some were denied . We are working with reimbursement consultants in Germany who have a successful track record of securing adequate payment for new medical technologies. In light of the strong favorable clinical data for *iStent* , we anticipate that reimbursement will continue to improve in Germany.

Under German law, if a person has an income above a certain level, that person can opt out of the SHI and obtain private insurance. Approximately 10% of Germans have opted out and are covered by private insurance companies. Each of these private insurance companies makes its own decisions on individual claims. In general, the private insurance companies cover and pay for outpatient procedures listed on the EBM and that has been our experience to date with *iStent* insertion.

We have also made significant progress in reimbursement in Switzerland where the procedure that describes *iStent* insertion is on the list of approved outpatient procedures. This also means that the costs of any implants or supplies used during these procedures can be passed through for payment. Like Germany, coverage and payment decisions are decentralized, with 26 cantons and numerous private insurers determining coverage. To date, the vast majority of claims for *iStent* procedures have been processed and paid with no issues.

In France, our application for a code to describe *iStent* insertion and our application to add the *iStent* to the list of devices approved for pass through payment were denied in 2013. Following the publication of data on *iStent Inject* , we submitted new applications for both devices in 2014. In November 2015, the French government approved the *iStent* application for reimbursement. Unless there is a code and listing on the pass through list, the only opportunity for payment for the *iStent* in France would result from successful negotiations at the individual hospital level. There can be no assurance that the French government will approve pass through payment for *iStent* even though *iStent* has been approved for reimbursement.

In the United Kingdom, Spain and Italy, there are no codes that specifically describe the insertion of a trabecular stent. We do not anticipate this changing in Spain and Italy in the near future. In addition, there is no mechanism to provide incremental payment for the *iStent* when insertion is in conjunction with cataract surgery. Our success to date relies on our distributors in these countries negotiating with individual hospitals to cover the cost of inserting the *iStent* .

Reimbursement in other regions

We currently market the *iStent* in Australia , New Zealand and Canada . In Australia, we have been successful at including the *iStent* and *iStent Inject* on the pass through list so that the cost of the device is paid separately. In New Zealand, the vast majority of the population is covered under a publicly -funded, universal -coverage health system, with services provided by public, private and non -governmental sectors. W e have yet to achieve significant success with any of the public and major private payors in New Zealand . In Canada, the *iStent* and *iStent Inject* is paid through individual hospital budgets for glaucoma implants. We have yet to achieve a special funding pathway for *iStent* and *iStent Inject* in Canada and we will be subject to the limitation s of individual hospital budgets until Canadian Provinces provide a special funding pathway for our products.

Although we are not yet commercial in Japan, we believe that the current reimbursement structure that would apply to *iStent* insertion in conjunction with cataract surgery may support adequate reimbursement to both the facility and physician.

Competition

We are positioning our products and MIGS procedures for use instead of, or in combination with, prescription eye drop therapies that currently dominate the glaucoma treatment marketplace. To a lesser extent, we also compete with manufacturers of medical devices used in other surgical therapy procedures for treating glaucoma, including laser as well as more complex and invasive surgeries.

Many of our current and future competitors are large public companies or divisions of publicly -traded companies and have several competitive advantages, including:

- greater financial and human resources for product development, sales and marketing and patent litigation;
- significantly greater name recognition;
- longer operating histories;
- established relationships with healthcare professionals, customers and third -party payors;
- additional lines of products, and the ability to offer rebates or bundle products to offer higher discounts or incentives;
- more established sales and marketing programs and distribution networks; and
- greater experience in conducting research and development, manufacturing, clinical trials, preparing regulatory submissions and obtaining regulatory clearance or approval for drug and device products and marketing approved products.

Companies with competing products include Alcon, Inc. , a division of Novartis International AG (which has entered into a definitive agreement to acquire Transcend Medical, Inc. (Transcend) , a MIGS competitor), Abbott Medical Optics Inc., Allergan plc (which has entered into a definitive merger agreement with Pfizer, Inc., pursuant to which the two companies intend to combine), STAAR Surgical Company, Lumenis Ltd., NeoMedix,Inc. and Ellex Medical Lasers Limited. Alcon, Inc. and Abbott Medical Optics Inc. are the leading manufacturers of aqueous shunts, and Alcon, Inc. also markets the EX -PRESS Glaucoma Filtration Device and, upon its completion of the Transcend acquisition, will be a manufacturer of a MIGS device. Lumenis Ltd. is a leading manufacturer of SLT equipment. Neo M edix, Inc. markets an electrosurgical device and Ellex Medical Lasers Limited markets a canaloplasty device that some physicians employ to lower intraocular pressure in glaucoma.

In addition to these current competitors, we may also in the future compete with manufacturers of alternative technologies to treat glaucoma. We are aware of several companies, including Transcend (which has entered into a definitive agreement to be acquired by Alcon, Inc .), AqueSys, Inc. (which was recently acquired by Allergan plc, a publicly traded company, which has entered into a definitive merger agreement with Pfizer, Inc., pursuant to which the two companies intend to combine), InnFocus Inc. and Ivantis Inc. , that are conducting FDA -approved IDE clinical trials or have filed for regulatory approval of MIGS devices. These products or other products that may be developed could demonstrate better safety or effectiveness, clinical results, ease of use or lower costs than our *iStent* or other products under development. If approved for marketing, these devices may compete directly with the *iStent* and our products under development. If any of these alternative technologies gain market acceptance, this may reduce demand for our primary product, the *iStent* , as well as for our products in development .

In addition to competing for market share for our products, we also compete against these companies for personnel, including qualified sales representatives that are necessary to grow our business, as well as scientific and clinical personnel from universities and research institutions that are important to our research and development efforts.

We believe the principal competitive factors in our market include:

- improved outcomes for glaucoma;
- acceptance by ophthalmic surgeons;
- ease of use and reliability;
- product price and availability of reimbursement;
- technical leadership;
- effective marketing and distribution; and

- speed to market.

Facilities, Manufacturing and Distribution

We occupy approximately 2 3 , 915 square feet at our corporate headquarters facilities located in Laguna Hills, California under a lease that expires on September 30, 2016. All of our headquarters -based employees, including our manufacturing and dis tribution employees, work at these facilit ies . While these facilit ies are sufficient for our current needs, we will require additional space as our business expands. Accordingly, we entered into a sublease for an approximately 37,700 square foot facility located in San Clemente, California effective September 1, 2015, as well as a five -year lease for these premises that takes effect January 1, 2017 upon expiration of the sublease. We plan for this facility to serve as our headquarters beginning sometime in 2016. Our international subsidiaries also lease facilities in Australia, Canada, Germany and Japan.

We manufacture, inspect, package and ship finished products from our Laguna Hills facility. We source components used in our proprietary manufacturing process from outside vendors and we assemble them to produce *iStent* devices and disposable insertion instruments. These components include both off -the -shelf materials and custom made parts. The *iStent* device and some insertion instrument components are supplied by single vendors. While we believe that there are at least several other vendors that could make any one of these items, we maintain a minimum inventory of three to six months' supply to help mitigate any supply interruptions. We source the heparin used in our *iStent* heparin coating from one supplier. We maintain a stock of several years' worth of heparin material and have FDA approval to retest and extend the shelf life of the material indefinitely for U.S. product.

We have received International Standards Organization (ISO) 13485 certification, which includes design control requirements. Our manufacturing processes have been validated as required by the FDA and other regulatory bodies. As a medical device manufacturer, our manufacturing facility and the facilities of our critical suppliers are subject to periodic inspection by the FDA and other regulatory agencies. To date, FDA and CE manufacturing audits conducted at our facilities have noted no significant deficiencies or findings requiring remediation.

We have significantly increased manufacturing output since the commercial launch of the *iStent* in 2012. We believe we are well -positioned to continue advancing our manufacturing technology, capacity and efficiency going forward.

Intellectual Property

We believe that the strength of our competitive position will depend substantially upon our ability to obtain and enforce intellectual property rights protecting our technology. We file for patents for new patentable technologies relevant to our business and utilize other forms of intellectual property protection to strategically protect our intellectual property. We believe that our intellectual property portfolio can be leveraged into new products and potential additional indications for our technology. In addition, we may also review and attempt to acquire rights in third -party patents and applications that are strategically valuable to us.

Patents

As of December 31, 2015, we owned or exclusively licensed in certain fields of use 124 issued patents, of which we owned 52 that were issued in the United States and 61 that were issued outside of the United States, and 80 pending patent applications, of which we owned 29 that were filed in the United States and 21 that were filed outside of the United States. We also granted to DOSE Medical certain exclusive rights and licenses outside our licensed fields of use under certain of our owned patents and patent applications. Our issued patents that protect our commercial products and current product pipeline will expire between 2020 and 2033. While we have pursued and continue to pursue patent protection for our technologies, we may, from time to time, abandon certain patents and patent applications for business reasons.

Our U.S. patents include a variety of claims related to devices and methods for treating glaucoma with ab -interno surgical procedures, which are procedures initiated from within the anterior chamber of the eye and accessed

through an opening in the clear corneal tissue. Our pending U.S. patent applications, if issued with their present claims, relate to the same field and potentially other fields of use.

From March 2013 to October 2015, we were engaged in a dispute with Transcend (which has entered into a definitive agreement to be acquired by Alcon, Inc., a divisi on of Novartis International AG) as to whether or not Transcend's CyPass Micro ‑Stent infringed our patents. On October 29, 2015, we entered into a settlement agreement with Transcend to resolve the patent litigation then pending between us before the U.S. District Court for the District of Delaware. Under the settlement agreement, we granted Transcend a covenant not to sue Transcend for patent infringement in connection with Transcend's CyPass Micro ‑Stent devices, appliers and delivery systems. In exchange, Transcend granted us a conditional covenant not to challenge the validity or enforceability of any of our patents and will make quarterly payments to us equal to 1% of future net sales of the CyPass Micro ‑Stent devices until April 8, 2022 or up to a maximum aggregate payment amount of $6.0 million. In connection with our settlement, we filed a joint stipulation of dismissal with prejudice of all of our respective claims against each other in this matter, with each of us responsible for our own legal expenses. The court dismissed the matter with prejudice on October 29, 2015, thereby eliminating the need for the trial, which was scheduled to begin on November 2, 2015. In connection with entering into the settlement agreement, we agreed to pay The Regents of The University of California (the University) 33% of any payments we receive from Transcend pursuant to the settlement agreement. For additional information relating to our agreement with the University, see "Intellectual Property—Intellectual property agreements."

Before dismissal, the court ruled on Transcend's motion for summary judgment on various invalidity grounds. While the court denied Transcend summary judgment on almost all grounds, the court did issue an order granting summary judgment that certain dependent claims using the term "choroid" were indefinite and invalid. Although this order did not become a final judgment due to the dismissal, there would be no guarantee that the order would not negatively affect an analysis of the validity of these claims in addition to a limited number of claims in other patents that we own covering the *iStent Supra* if such patents are challenged in the future.

The ophthalmology industry in which we operate has been subject to a large number of patent filings and patent infringement litigation. Whether we infringe any patent claim owned by a third party will not be known with certainty unless and until a court interprets the patent claim in the context of litigation. If an infringement allegation is made against us, we may seek to invalidate the asserted patent claim and may allege non ‑infringement of the asserted patent claim. Also, for business reasons, we may take similar actions before any such infringement allegation is made. In order for us to invalidate a U.S. patent claim, we would need to rebut the presumption of validity afforded to issued patents in the United States with clear and convincing evidence of invalidity, which is a high burden of proof. Similar or greater effort and proof may be required to invalidate foreign patents owned by third parties, including those owned by our competitors.

Trademarks

Glaukos, our logo, iStent, iStent Supra, iStent Inject and iPrism are registered trademarks of our company in the United States. Glaukos, iStent, iStent Inject, iStent Supra and iDose are registered trademarks of our company in the European Union. We have registered trademarks for Glaukos in Canada, Japan and Mexico. We have registered trademarks for iStent in Australia, Canada, Chile, Japan, Mexico and Switzerland. We have pending trademark applications for iStent in Argentina, Brazil and Columbia. We have a pending trademark application for iDose TR in the United States. We have pending trademark applications for iDose in Australia, Canada, Japan and the United States. We have pending trademark applications for iPrism in Australia, Canada, Europe and Japan. We have pending trademark applications for iStent Inject in Australia, Canada and Japan. We also use MIGS as an unregistered trademark .

Trade secrets

We may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and manufacturing process in part by confidentiality and invention assignment agreements with employees, under which they are bound to assign to us inventions made during the term of their employment unless excluded pursuant to California Labor Code Section 2870. These agreements further prohibit our employees from using, disclosing, or bringing onto the premises any proprietary information belonging to a third party. In addition, most of our consultants, scientific advisors and contractors are required to sign

agreements under which they must assign to us any inventions that relate to our business. These agreements also prohibit these third parties from incorporating into any inventions the proprietary rights of third parties without informing us. It is our policy to require all employees to document potential inventions and other intellectual property in laboratory notebooks and to disclose inventions to patent counsel using invention disclosure forms.

We also rely on confidentiality restrictions and trade secret protection to protect our technology. We generally require our consultants and other parties who may be exposed to our proprietary technology to sign non‑disclosure agreements that prohibit such parties from disclosing or using our proprietary information except as may be authorized by us.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know‑how and inventions.

Intellectual property agreements

In January 2007, we entered into an agreement with GMP Vision Solutions, Inc. (GMP) to acquire certain in‑process research and development. In connection with the agreement, we agreed to make periodic royalty payments based on revenues received for royalty‑bearing products and periodic royalty payments at a higher rate for all amounts received in connection with the grant of licenses or sublicenses of the related intellectual property. In December 2012, we entered into an agreement with GMP pursuant to which we paid GMP $1.0 million for a 90‑day option to buy out all remaining royalties payable to GMP. In April 2013, the option expired unexercised and as provided in the agreement, the $1.0 million payment satisfied the obligation to pay the first $1.0 million in royalties earned beginning on January 1, 2013.

In November 2013, we entered into an agreement with GMP pursuant to which we bought out all remaining royalties payable to GMP in exchange for the issuance of $17.5 million in promissory notes payable to GMP and a party related to GMP. For additional information relating to the terms of these notes, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—Indebtedness.”

In December 2014, we entered into an agreement with the University to quiet title to our entire ownership of certain patents and patent applications, or the Patent Rights, to which Dr. Richard Hill contributed while he was both a consultant for us and a faculty member at the University. In connection with the agreement, we agreed to pay to the University $2.7 million in 2015 and to make periodic payments to the University equal to a low single‑digit percentage of worldwide net sales, beginning in 2015, of certain current and future products, including our *iStent* products, with a required minimum annual payment of $500,000 during the term of the agreement. The University has a security interest in all tangible assets owned by us. Our agreement with the University will expire upon the expiration of the last to expire of the Patent Rights, which is currently expected to be in 2022.

On October 29, 2015, we entered into the settlement agreement with Transcend (which has entered into a definitive agreement to be acquired by Alcon, Inc., a division of Novartis International AG, which is a publicly traded multinational pharmaceutical company based in Basel, Switzerland) whereby we granted Transcend a covenant not to sue for patent infringement in connection with certain Transcend products and released Transcend from any and all liability for past infringement of our patents. Transcend granted us a conditional covenant not to challenge the validity or enforceability of any of our patents, and agreed to make royalty payments equal to 1% of future net sales of certain Transcend products in countries where we have patent protection. Transcend’s royalty obligation continues until April 8, 2022, or up to a maximum aggregate payment amount of $6.0 million, whichever occurs first. In connection with entering into the settlement agreement, we agreed to pay the University 33% of any payments we receive from Transcend pursuant to the settlement agreement .

Government Regulation

Our products and operations are subject to extensive and rigorous regulation by the FDA and other federal, state and local authorities, as well as foreign regulatory authorities. The FDA regulates, 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 (such as *iStent*), as well as combination drug/device products (such as *iDose*) in the United States to assure the safety and effectiveness of medical products for their intended use. The Federal Trade Commission also regulates the advertising of our products. Further, we are subject to laws directed at preventing fraud and abuse, which subject our sales and marketing, training and other practices to government scrutiny.

U.S. government regulation—medical devices

Unless an exemption applies, each new or significantly modified medical device we seek to commercially distribute in the United States will require either a premarket notification to the FDA requesting permission for commercial distribution under Section 510(k) of the Federal Food, Drug and Cosmetic Act (FDCA) also referred to as a 510(k) clearance, or approval from the FDA of a PMA application. Both the 510(k) clearance and PMA processes can be expensive, and lengthy, and require payment of significant user fees, unless an exemption is available.

Device classification

Under the FDCA, medical devices are classified 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 control needed to provide reasonable assurances with respect to safety and effectiveness.

Class I devices are those for which safety and effectiveness can be reasonably assured by adherence to a set of regulations, referred to as General Controls, which require compliance with the applicable portions of the FDA's Quality System Regulation (QSR), facility registration and product listing, reporting of adverse events and malfunctions, and appropriate, truthful and non -misleading labeling and promotional materials. Some Class I devices, also called Class I reserved devices, also require premarket clearance by the FDA through the 510(k) premarket notification process described below. Most Class I products are exempt from the premarket notification requirements.

Class II devices are those that are subject to the General Controls, as well as Special Controls, which can include performance standards, guidelines and postmarket surveillance. Most Class II devices are subject to premarket review and clearance by the FDA. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process. Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is "substantially equivalent," as defined in the statute, to either:

- a device that was legally marketed prior to May 28, 1976, the date upon which the Medical Device Amendments of 1976 were enacted, or
- another commercially available, similar device that was cleared through the 510(k) process.

To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence.

After a 510(k) notice is submitted, the FDA determines whether to accept it for substantive review. If it lacks necessary information for substantive review, the FDA will refuse to accept the 510(k) notification. If it is accepted for filing, the FDA begins a substantive review. By statute, the FDA is required to complete its review of a 510(k) notification within 90 days of receiving the 510(k) notification. As a practical matter, clearance often takes longer, and clearance is never assured. Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including clinical data, to make a determination regarding substantial equivalence, which

may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, could require a PMA application. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination regarding whether a new premarket submission is required for the modification of an existing device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA application is obtained. If the FDA requires us to seek 510(k) clearance or approval of a PMA application for any modifications to a previously cleared product, we may be required to cease marketing or recall the modified device until we obtain this clearance or approval. In addition, in these circumstances, we may be subject to significant regulatory fines or penalties for failure to submit the requisite PMA application(s). In addition, the FDA is currently evaluating the 510(k) process and may make substantial changes to industry requirements.

If the FDA determines that the device is not "substantially equivalent" to a predicate device, or if the device is automatically classified into Class III, the device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA approval process, or seek reclassification of the device through the *de novo* process. Pursuant to amendments to the statute in 2012, a manufacturer can also submit a petition for direct *de novo* review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents a moderate or low risk.

Class III devices include devices deemed by the FDA to pose the greatest risk such as life ‑supporting or life ‑sustaining devices, or implantable devices, in addition to those deemed not substantially equivalent following the 510(k) process. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the General Controls and Special Controls described above. Therefore, these devices are subject to the PMA application process, which is generally more costly and time consuming than the 510(k) process. Through the PMA application process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA's satisfaction. Accordingly, a PMA application typically includes, but is not limited to, extensive technical information regarding device design and development, pre ‑clinical and clinical trial data, manufacturing information, labeling and financial disclosure information for the clinical investigators in device studies. The PMA application must provide valid scientific evidence that demonstrates to the FDA's satisfaction reasonable assurance of the safety and effectiveness of the device for its intended use.

The investigational device process

In the United States, absent certain limited exceptions, human clinical trials intended to support medical device clearance or approval require an IDE application. Some types of studies deemed to present "non ‑significant risk" are deemed to have an approved IDE once certain requirements are addressed and Institutional Review Board (IRB) approval is obtained. If the device presents a "significant risk" to human health, as defined by the FDA, the sponsor must submit an IDE application to the FDA and obtain IDE approval prior to commencing the human clinical trials. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of subjects. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate institutional review boards at the clinical trial sites. There can be no assurance that submission of an IDE will result in the ability to commence clinical trials, and although the FDA's approval of an IDE allows clinical testing to go forward for a specified number of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and efficacy, even if the trial meets its intended success criteria.

All clinical trials must be conducted in accordance with the FDA's IDE regulations that govern investigational device labeling, prohibit promotion and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with the FDA's regulations for institutional review board approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable, or, even if the intended safety and

efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant marketing approval or clearance of a product. The commencement or completion of any clinical trial may be delayed or halted, or be inadequate to support approval of a PMA application, for numerous reasons, including, but not limited to, the following:

- the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- patients do not enroll in clinical trials at the rate expected;
- patients do not comply with trial protocols;
- patient follow ‑up is not at the rate expected;
- patients experience adverse events;
- patients die during a clinical trial, even though their death may not be related to the products that are part of our trial;
- device malfunctions occur with unexpected frequency or potential adverse consequences;
- institutional review boards and third ‑party clinical investigators may delay or reject the trial protocol;
- third ‑party clinical investigators decline to participate in a trial or do not perform a trial on the anticipated schedule or consistent with the clinical trial protocol, good clinical practices or other FDA requirements;
- we or third ‑party organizations do not perform data collection, monitoring and analysis in a timely or accurate manner or consistent with the clinical trial protocol or investigational or statistical plans;
- third ‑party clinical investigators have significant financial interests related to us or our study such that the FDA deems the study results unreliable, or we or investigators fail to disclose such interests;
- regulatory inspections of our clinical trials or manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials;
- changes in government regulations or administrative actions;
- the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or efficacy; or
- the FDA concludes that our trial design is inadequate to demonstrate safety and efficacy.

The PMA approval process

Following receipt of a PMA application, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If it is, the FDA will accept the application for filing and begin the review. The FDA, by statute and by regulation, has 180 days to review a filed PMA application, although the review of an application more often occurs over a significantly longer period of time. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies communicated by the FDA. The FDA considers a PMA or PMA supplement to have been voluntarily withdrawn if an applicant fails to respond to an FDA request for information (*e.g.* , major deficiency letter) within a total of 360 days. Before approving or denying a PMA, an FDA advisory committee may review the PMA at a public meeting and provide the FDA with the committee's recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. Prior to approval of a PMA, the FDA may conduct a bioresearch monitoring inspection of the clinical trial data and clinical trial sites, and a QSR inspection of the manufacturing facility and processes. Overall, the FDA review of a PMA application generally takes between one and

three years, but may take significantly longer. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- the device may not be shown safe or effective to the FDA's satisfaction;
- the data from pre‑clinical studies and clinical trials may be insufficient to support approval;
- the manufacturing process or facilities may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require additional data.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter, or an approvable letter, which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the PMA, or the PMA is withdrawn and resubmitted when the data are available. The PMA process can be expensive, uncertain and lengthy and a number of devices for which FDA approval has been sought by other companies have never been approved by the FDA for marketing.

New PMA applications or PMA supplements may be required for modification to the manufacturing process, labeling, device specifications, materials or design of a device that has been approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive technical or clinical data or the convening of an advisory panel, depending on the nature of the proposed change.

In approving a PMA application, the FDA may also require some form of postmarket studies or postmarket surveillance, whereby the applicant follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional safety and effectiveness data for the device. FDA may also require postmarket surveillance for certain devices cleared under a 510(k) notification, such as implants or life‑supporting or life‑sustaining devices used outside a device user facility. The FDA may also approve a PMA application with other post‑approval conditions intended to ensure the safety and effectiveness of the device, such as, among other things, restrictions on labeling, promotion, sale, distribution and use.

Because of the indication we chose to pursue for the *iStent* in the United States, the FDA required that we undergo the more rigorous PMA process. The majority of the devices currently marketed in the United States for the treatment of glaucoma have been cleared via the 510(k) process. The FDA considered the *iStent* to be a "first in class" device that was not substantially equivalent to any currently marketed device.

The FDA approved the *iStent* PMA on June 25, 2012, for the indication for use in combination with cataract surgery for the reduction of intraocular pressure in adult patients with mild‑to‑moderate open‑angle glaucoma currently treated with prescription eye drops. The FDA imposed conditions of approval, including three postmarket studies, and a requirement that we implement a three‑part training program for physicians who will use the *iStent* device.

We are required to file new PMA applications or PMA supplement applications for significant modifications to the manufacturing process, labeling and design of a device for which we have received approval through the PMA approval process.

Post ‑approval requirements

After the FDA permits a device to enter commercial distribution, numerous regulatory requirements apply. These include, but are not limited to:

- the registration and listing regulation, which requires manufacturers to register all manufacturing facilities and list all medical devices placed into commercial distribution;
- the QSR, which requires manufacturers, including third ‑party manufacturers, to follow elaborate design, testing, production, control, supplier/contractor selection, complaint handling, documentation and other quality assurance procedures during the manufacturing process;
- labeling regulations and unique device identification requirements;
- advertising and promotion requirements;
- restrictions on sale, distribution or use of a device;
- PMA annual reporting requirements;
- the FDA's general prohibition against promoting products for unapproved or "off ‑label" uses;
- the Medical Device Reporting, or MDR, regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to reoccur;
- medical device correction and removal 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;
- recall requirements, including a mandatory recall if there is a reasonable probability that the device would cause serious adverse health consequences or death;
- an order of repair, replacement or refund;
- device tracking requirements; and
- postapproval study and postmarket surveillance requirements.

Our facilities, records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. Failure to comply with the applicable United States medical device regulatory requirements could result in, among other things, warning letters, untitled letters, fines, injunctions, consent decrees, civil penalties, unanticipated expenditures, repairs, replacements, refunds, recalls or seizures of products, operating restrictions, total or partial suspension of production, the FDA's refusal to issue certificates to foreign governments needed to export products for sale in other countries, the FDA's refusal to grant future premarket clearances or approvals, withdrawals or suspensions of current product clearances or approvals and criminal prosecution.

U.S. government regulation—drug delivery implant

In the United States, the FDA regulates drugs and combination drug/device products under the FDCA and related regulations. Drugs are also subject to other federal, state and local statutes and regulations, which along with the FDCA govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, advertising, promotion and marketing, distribution, post ‑approval monitoring and reporting, and import and export of pharmaceutical products. Failure to comply with the applicable U.S. regulatory requirements at any time during the drug product development process, approval process or post ‑approval, may subject an applicant to administrative or judicial sanctions, including refusal by the FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of

profits, or civil or criminal investigations and penalties brought by FDA and the Department of Justice, or other governmental entities. Any agency or judicial enforcement action could have a material adverse effect on us.

The steps required before a drug may be approved for marketing in the United States generally include:

- completion of preclinical laboratory tests and animal tests conducted in compliance with the FDA's Good Laboratory Practices;
- the submission to the FDA of an IND which must become effective before human clinical trials commence in the United States;
- approval by an IRB at each clinical trial site before each trial may be initiated;
- obtaining informed consent from the participants in a clinical trial;
- performance of adequate and well -controlled human clinical trials to establish the safety and efficacy of the product for each intended use and conducted in accordance with Good Clinical Practices (GCP);
- satisfactory completion of an FDA pre -approval inspection of the facility or facilities at which the product is manufactured to assess compliance with FDA's current Good Manufacturing Practices (cGMPs) to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- the submission to the FDA of an NDA;
- satisfactory completion of a potential review by an FDA advisory committee, if applicable; and
- FDA acceptance, review and approval of the NDA.

The investigational new drug process

An IND application is a request for authorization from the FDA to administer an investigational drug to humans. Such authorization must be obtained prior to administration to humans of any new drug or dosage form, including a new use of a previously approved drug, that is not the subject of an approved new drug application, or NDA, except under limited circumstances.

To conduct a clinical study of an investigational new drug product, we are required to file an IND with the FDA. The IND submission must include the general investigational plan and the protocol(s) for human studies, as well as results of animal studies or other human studies, as appropriate, analytical data and any available clinical data or literature to support the use of the investigational new drug. An IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to the proposed clinical trials as outlined in the IND. If FDA raises questions, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before clinical trials can begin. Accordingly, submission of an IND may or may not result in the FDA allowing clinical trials to begin. A separate submission to an existing IND application must also be made for each successive clinical trial conducted during product development.

Clinical trials involve the administration of the investigational drug to patients under the supervision of qualified investigators in accordance with GCPs. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Additionally, approval must also be obtained from the IRB at each clinical site before the trials may be initiated. The IRB will consider, among other things, ethical factors, the safety of human subjects and the possible liability of the institution. The IRB must also monitor the trial until completed. All participants in our clinical trials must provide their informed consent in writing. In addition, there are requirements and industry guidelines that require the posting of ongoing clinical trials on public registries, and the disclosure of designated clinical trial results. The IRB must also review and approve all clinical trial recruitment plans and materials.

The clinical investigation of an investigational drug product is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined. The three phases of investigational new drug investigation are as follows:

- *Phase I.* Phase I includes the initial introduction of an investigational new drug into humans. Phase I clinical trials are typically closely monitored and may be conducted in patients with the target disease or condition or healthy volunteers. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational drug product in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness. During Phase I clinical trials, sufficient information about the investigational drug's pharmacokinetics and pharmacological effects may be obtained to permit the design of well ‑controlled and scientifically valid Phase II clinical trials. The total number of participants included in Phase I clinical trials varies, but is generally in the range of 20 to 80.
- *Phase II.* Phase II includes the controlled clinical trials conducted to preliminarily evaluate the effectiveness of the investigational drug for a particular indication in patients with the disease or condition under study, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks associated with the drug product. Phase II clinical trials are typically well ‑controlled, closely monitored, and conducted in a limited patient population, usually involving no more than several hundred participants.
- *Phase III.* Phase III clinical trials are generally controlled clinical trials conducted in an expanded patient population generally at multiple clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the drug product has been obtained, and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit ‑risk profile of the investigational drug product, and to provide an adequate basis for product approval and adequate information for product labeling. Phase III clinical trials usually involve several hundred to several thousand participants. In most cases, the FDA requires two adequate and well ‑controlled Phase III clinical trials to demonstrate the efficacy of the drug. The FDA has the legal discretion to approve a drug on the basis of a single well ‑controlled clinical trial. In practice, the agency often requires that such a trial meet higher standards in terms of size, robustness and statistical significance, and it may restrict approval on the basis of single trial to situations in which there is a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

The FDA's primary objectives in reviewing an IND are to assure the safety and rights of patients and to help assure that the quality of the investigation will be adequate to permit an evaluation of the drug's effectiveness and safety. The decision to terminate development of an investigational drug product may be made by either the FDA, an IRB or ethics committee, or by the study sponsor for various reasons. Clinical trials may be overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access that only the group maintains to available data from the study. Suspension or termination of development during any phase of clinical trials can occur if it is determined that the participants or patients are being exposed to an unacceptable risk to health. Other reasons for suspension or termination may include changes in business objectives or the economic environment.

The NDA approval process

In order to obtain approval to market a drug product in the United States, a marketing application must be submitted to the FDA that includes data to establish the safety and effectiveness of the new drug product for the proposed indication. The NDA includes all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. The NDA filing must also be accompanied by a substantial user fee, although there may be some instances in which the user fee is waived.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. The FDA has substantial discretion in the approval process and may refuse to accept any application or decide that the data is insufficient for approval and require additional preclinical, clinical or other studies. If the FDA requests additional information rather than accept an NDA for filing, the NDA must be resubmitted with the additional information and is subject to payment of additional user fees. The resubmitted application is also subject to review before the FDA accepts it for filing.

Once the NDA has been accepted for filing, the FDA begins an in ‑depth substantive review and sets a Prescription Drug User Fee Act date that informs the applicant of the specific date by which the FDA intends to complete its review. The FDA has agreed to certain performance goals in the review of NDAs through a two ‑tiered classification system, Standard Review and Priority Review. Priority Review designation is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. The FDA endeavors to review applications subject to Standard Review within 10 to 12 months, whereas the FDA's goal is to review Priority Review applications within six to eight months, depending on whether the drug is a new molecular entity. The review process is often extended by FDA requests for additional information or clarification. The FDA reviews NDAs to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. Before approving an NDA, the FDA will review the proposed product labeling and may request changes. FDA will also inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. In addition, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines the application, manufacturing process or manufacturing facilities are not acceptable, it will communicate the deficiencies to the applicant and often will request additional testing or information. Even with the submission of additional information, the FDA ultimately may decide that the application does not satisfy the regulatory standards for approval.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter to indicate that the review cycle for an application is complete and that the application is not ready for approval. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA may ultimately decide that an application does not satisfy the regulatory criteria for approval. If, or when, the deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

The clinical testing and drug approval process requires substantial time, effort and financial resources, and each may take several years to complete. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all. Even if the FDA approves a product, the agency may limit the approved indications for use, impose prominent warnings, or place other conditions on approval that could restrict the commercial application of the products, such as special risk management measures through a Risk Evaluation and Mitigation Strategy. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Section 505 of the FDCA describes three types of new drug applications: (1) an application that contains full reports of investigations of safety and effectiveness (section 505(b)(1)); (2) an application that contains full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference (section 505(b)(2)); and (3) an application that contains information to show that the proposed product is identical in active ingredient, dosage form, strength, route of administration, labeling, quality, performance characteristics, and intended use, among other things, to a previously approved product (section 505(j)).

Our *iDose* implant may be eligible for the Section 505(b)(2) application pathway if and when we are prepared to submit an application for marketing to the FDA. Section 505(b)(2) expressly permits the FDA to rely, in approving a new drug application, on data not developed by the applicant. Thus, if a 505(b)(2) applicant can establish that reliance on

the FDA's previous findings of safety and effectiveness is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. We are pursuing a Section 505(b)(2) NDA regulatory strategy for our *iDose* implant, which we expect will allow us to rely in our NDA filing on certain nonclinical and clinical safety findings made by the FDA in previous approvals. For changes to a previously approved drug product, an application may rely on the FDA's finding of safety and effectiveness of the previously approved drug, coupled with the information needed to support the change from the approved drug product. The additional information could be new studies conducted by the applicant or published data. The FDA may approve the new product candidate for all, or some, of the label indications for which the reference drug has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

The filing or approval of a Section 505(b)(2) application may be delayed due to patent or exclusivity protections covering an approved product. Section 505(b)(2) applications must include patent certifications and must provide notice of certain patent certifications to the NDA holder and patent owner. A Section 505(b)(2) application may be granted three years of market exclusivity if one or more of the clinical investigations, other than bioavailability/bioequivalence studies, was essential to approval of the application and was conducted or sponsored by the applicant.

Circumstances could change that may cause a Section 505(b)(2) application for our product to no longer be an appropriate pathway. For example, if an equivalent drug product were approved before our application is submitted, the applicable pathway for our drug product might be an Abbreviated New Drug Application (ANDA). An ANDA seeks approval of a drug product that has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use (labeling) as a so -called "reference listed drug" approved under an NDA with full supporting data to establish safety and effectiveness. Limited exceptions exist to this ANDA sameness requirement, including certain limited variations approved by the FDA through a special petition process. An ANDA must contain certifications relating to patents for the reference listed drug. An ANDA also generally contains limited clinical data to demonstrate that the product covered by the ANDA is absorbed in the body at the same rate and to the same extent as the reference listed drug, which is known as bioequivalence. In addition, the ANDA must contain information regarding the manufacturing processes and facilities that will be used to ensure product quality, and must contain certifications to patents listed with the FDA for the reference listed drug.

Post -approval regulation

After regulatory approval of a drug or combination drug/device product is obtained under an NDA, we are required to comply with pervasive and continuing regulation by the FDA, including, among other things, requirements relating to drug listing and registration, recordkeeping, periodic reporting, product sampling and distribution, advertising, marketing and promotion and reporting of adverse experiences with the product. For example, as a condition of approval of an NDA, the FDA may require post -marketing testing, including Phase IV clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. In addition, the holder of an approved NDA would be required to report, among other things, certain adverse events and production problems to the FDA, and to provide updated safety and efficacy information to the FDA. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label, and even if the FDA approves a product, it may limit the approved indications for use for the product or impose other conditions, including labeling or distribution restrictions or other risk -management mechanisms. For a combination drug/device product, such as our *iDose* implant, certain device reporting requirements might also apply, such as MDR requirements and reports of corrections and removal.

Quality control and manufacturing procedures must continue to conform to cGMP after approval. In addition, medical device quality system regulations would apply to the device component of a combination drug/device product, either all the QSR regulations or particular QSR regulations supplementing the drug cGMP in accordance with FDA regulations in 21 C.F.R. Part 4. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP and QSR. In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP or QSR and impose reporting and documentation requirements upon us and any third -party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP, QSR, and other aspects of regulatory compliance.

After approval, most changes to the approved product, such as adding new indications or other labeling claims, as well as some manufacturing and supplier changes, are subject to prior FDA review and approval of a new NDA or an NDA supplement. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the similar procedures in reviewing NDA supplements as it does in reviewing NDAs. The manufacturer and/or sponsor under an approved NDA are also subject to annual product and establishment user fees, as well as new application fees for certain supplemental applications.

Discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal or recall of the product from the market or other voluntary, FDA ‑initiated or judicial action that could delay or prohibit further marketing. Other potential consequences include, among other things:

- fines, warning letters or holds on post ‑approval clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. In addition, the FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off ‑label uses, and a company that is found to have improperly promoted off ‑label uses may be subject to significant liability.

New government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development and/or could significantly impact the requirements imposed on us after approval.

Available special regulatory procedures

Formal meetings

In the United States, there are different types of official meetings that may occur between us and the FDA. Each meeting type is subject to different procedures. Conclusions and agreements from each of these meetings are captured in the official final meeting minutes issued by the FDA.

Advice from the FDA is typically provided based on questions concerning quality (chemistry, manufacturing and controls testing), pre ‑clinical testing and clinical studies, and pharmacovigilance plans and risk ‑ management programs. Advice is not legally binding with regard to any future marketing application for the drug product.

To obtain binding commitments from the FDA on the design and size of clinical trials intended to form the primary basis of an effectiveness claim for a new drug product, Special Protocol Assessment (SPA) procedures are available. Where the FDA agrees to an SPA, the agreement may not be changed by either the sponsor or the FDA except if the sponsor and the FDA agree to a change, or a senior FDA official determines that a substantial scientific issue essential to determining the safety or effectiveness of the product was identified after the testing began. An SPA is not binding if new circumstances arise, and there is no guarantee that a study will ultimately be adequate to support an approval even if the study is conducted according to the terms of an SPA.

Pediatric development

In the United States, the FDCA provides for an additional six months of marketing exclusivity for a drug if reports are filed of investigations studying the use of the drug product in a pediatric population in response to a written request from the FDA.

In addition, NDAs must contain data (or a proposal for post -marketing activity) to assess the safety and effectiveness of an investigational drug product for the claimed indications in all relevant pediatric populations in order to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults or full or partial waivers if certain criteria are met. Discussions about pediatric development plans can be discussed with the FDA at any time, but usually occur any time between the end -of -Phase II meeting and submission of the NDA.

Priority review or standard review

Based on results of Phase III clinical trials, an NDA may receive priority or standard review from the FDA. Priority review is given where preliminary estimates indicate that a product, if approved, would provide a significant improvement in safety or effectiveness of the treatment, diagnosis or prevention of a serious condition. Effective October 1, 2012, where an application receives priority review, the target date for FDA action will be eight months from submission in the case of an application for a new chemical entity and six months from submission in the case of products that do not contain a new chemical entity. Where an application receives standard review, the target date for FDA action will be 12 months from submission in the case of an application for a new chemical entity and 10 months from submission in the case of products that do not contain a new chemical entity.

Other healthcare laws

We are also subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we conduct our business. These laws include, without limitation, state and federal anti -kickback, fraud and abuse, false claims, and physician sunshine laws and regulations.

The federal Anti -Kickback Statute prohibits, among other things, the offer, receipt, or payment of remuneration in exchange for or to induce the referral of patients or the use of products or services that would be paid for in whole or part by Medicare, Medicaid or other federal healthcare programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced price items and services. The government has enforced the Anti -Kickback Statute to reach large settlements with healthcare companies based on sham research or consulting and other financial arrangements with physicians. Further, a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti -Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act (FCA). Many states have similar laws that apply to their state healthcare programs as well as private payors. Violations of the Anti -Kickback Statute can result in exclusion from federal healthcare programs and substantial civil and criminal penalties.

The FCA imposes liability on persons who, among other things, present or cause to be presented false or fraudulent claims for payment by a federal healthcare program. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. Manufacturers can be held liable under these laws if they are deemed to “cause” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off -label. Actions under the FCA may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the FCA can result in significant monetary penalties and treble damages. The federal government is using the FCA, and the accompanying threat of significant liability, in its investigation and prosecution of device companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other improper sales and marketing practices. The government has obtained multi -million and multi -billion dollar settlements under the FCA in addition to individual criminal convictions under applicable criminal statutes. In addition, companies have been forced to implement extensive corrective action

plans, and have often become subject to consent decrees or corporate integrity agreements, severely restricting the manner in which they conduct their business. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws. If our marketing, clinical trial recruitment, research or other arrangements, including consulting arrangements with physicians, were determined to violate anti -kickback or related laws, including the FCA, then our revenues could be adversely affected, which would likely harm our business, financial condition, and results of operations.

In addition, there has been a trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The PPACA, among other things, imposed new reporting requirements on certain device manufacturers for payments made by them to physicians and teaching hospitals, as well as certain ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (and up to an aggregate of $1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Device manufacturers were required to begin collecting data on August 1, 2013 and submit reports on aggregate payment data to the government for the first reporting period (August 1, 2013—December 31, 2013) by March 31, 2014, and were required to report detailed payment data for the first reporting period and submit legal attestation to the accuracy of such data by June 30, 2014. Thereafter, device manufacturers must submit reports by the 90th day of each subsequent calendar year. Certain states also mandate implementation of commercial compliance programs and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians.

The shifting commercial compliance environment and the need to build and maintain robust systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may violate one or more of the requirements. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

Regulation outside the United States

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing clinical trials and commercial sales and distribution of our products. 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 outside the United States before we can commence clinical trials or marketing of the product in those countries. 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 the European Economic Area (EEA) our *iStent* product is regulated as a medical device. Where a medical device is intended to administer a drug, the medical device will ordinarily be regulated as a medical device, while the medicinal product will be separately regulated as a medicinal product. However, when a drug -device combination product, such as *iDose* , is placed on the market as a single integral product that is intended exclusively for use in the given combination and that is not reusable, the entire product will be regulated as a medicinal product, although the device component will still need to comply with the so -called essential requirements applicable to medical devices.

Regulation of medical devices in the EEA

There is currently no premarket government review of medical devices in the EEA unless the device also contains a medicine or a blood derivative. However, all medical devices placed on the market in the EEA must meet the relevant essential requirements laid down in Annex I to Directive 93/42/EEC concerning medical devices, or the Medical Devices Directive. The most fundamental essential requirement is that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in a suitable manner. The European Commission has adopted various standards

applicable to medical devices. These include standards governing common requirements, such as sterilization and safety of medical electrical equipment, and product standards for certain types of medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards is viewed as the easiest way to satisfy the essential requirements as a practical matter. Compliance with a standard developed to implement an essential requirement also creates a rebuttable presumption that the device satisfies that essential requirement.

To demonstrate compliance with the essential requirements laid down in Annex I to the Medical Devices Directive, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Manufacturers usually have some flexibility to select conformity assessment procedures for a particular class of device and to reflect their circumstances, such as the likelihood that the manufacturer will make frequent modifications to its products. Conformity assessment procedures require an assessment of available clinical evidence, literature data for the product and post ‑market experience in respect of similar products already marketed. Except for low ‑risk medical devices, where the manufacturer can self ‑declare the conformity of its products with the essential requirements, a conformity assessment procedure requires the intervention of a notified body. Notified bodies are often private entities and are authorized or licensed to perform such assessments by government authorities. The notified body would typically audit and examine products' technical dossiers and the manufacturers' quality system. If satisfied that the relevant product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EEA. Once the product has been placed on the market in the EEA, the manufacturer must comply with requirements for reporting incidents and field safety corrective actions associated with the medical device.

In order to demonstrate safety and efficacy for their medical devices, manufacturers must conduct clinical investigations in accordance with the requirements of Annex X to the Medical Devices Directive and applicable European and ISO standards, as implemented or adopted in the EEA member states. Clinical trials for medical devices usually require the approval of an ethics review board and approval by or notification to the national regulatory authorities. Both regulators and ethics committees also require the submission of adverse event reports during a study and may request a copy of the final study report.

In September 2012, the European Commission adopted a Proposal for a Regulation of the European Parliament and of the Council on medical devices that will, if adopted, replace the existing Medical Devices Directive. After protracted negotiations, the proposal has now entered a so ‑called trilogue procedure involving the European Parliament, Commission and Council, in which all parties will seek to agree to a compromise position. If adopted, the Regulation is expected to enter into force sometime in 2016 and become applicable three years thereafter. In its current form it would, among other things, impose additional reporting requirements on manufacturers of high risk medical devices, impose an obligation on manufacturers to appoint a "qualified person" responsible for regulatory compliance, and provide for more strict clinical evidence requirements.

Regulation of medicinal products in the EEA

Medicinal Products require a marketing authorization before they may be placed on the market in the EEA. There are various application procedures available, depending on the type of product involved. The centralized procedure gives rise to marketing authorizations that are valid throughout the EEA. Applicants file marketing authorization applications with the European Medicines Agency (EMA)where they are reviewed by a relevant scientific committee, in most cases the Committee for Medicinal Products for Human Use (CHMP). The EMA forwards CHMP opinions to the European Commission, which uses them as the basis for deciding whether to grant a marketing authorization. The centralized procedure is compulsory for medicinal products that (1) are derived from specified biotechnology processes, (2) contain a new active substance (not yet approved on November 20, 2005) indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders, viral diseases or autoimmune diseases and other immune dysfunctions, (3) are orphan medicinal products or (4) are advanced therapy medicinal products (such as gene therapy, somatic cell therapy and tissue engineered products). For medicines that do not fall within these categories, an applicant may voluntarily submit an application for a centralized marketing authorization to the EMA, as long as the CHMP agrees that (i) the medicine concerned contains a new active substance (not yet approved on November 20, 2005), (ii) the medicine is a significant therapeutic, scientific, or technical

innovation, or (iii) if its authorization under the centralized procedure would be in the interest of public health. For those medicinal products for which the centralized procedure is not available, the applicant must submit marketing authorization applications to the national medicines regulators through one of three procedures: (1) a national procedure, which results in a marketing authorization in a single EEA member state; (2) the decentralized procedure, in which applications are submitted simultaneously in two or more EEA member states; and (3) the mutual recognition procedure, which must be used if the product has already been authorized in at least one other EEA member state, and in which the EEA member states are required to grant an authorization recognizing the existing authorization in the other EEA member state, unless they identify a serious risk to public health. A national procedure is only possible for one member state; as soon as an application is submitted in a second member state the mutual recognition or decentralized procedure will be triggered.

Marketing authorization applications must usually include the results of clinical trials. Clinical trials of medicinal products in the EEA must be conducted in accordance with EEA and national regulations and the International Conference on Harmonization guidelines on GCP. Prior to commencing a clinical trial in a particular EEA member state, the sponsor must obtain a clinical trial authorization from the competent authority and a positive opinion from an independent ethics committee.

There is scope for applicants to omit some or all of the pre ‑clinical and clinical trial data if the product falls within the definition of a generic of a reference product for which regulatory data exclusivity protection has expired. If a marketing authorization is granted for a medicinal product containing a new active substance, that product benefits from eight years of data exclusivity, during which generic marketing authorization applications referring to the data of that product may not be accepted by the regulatory authorities, and a further two years of market exclusivity, during which such generic products may not be placed on the market. The two ‑year period may be extended to three years if during the first eight years a new therapeutic indication with significant clinical benefit over existing therapies is approved.

For generic applications, the marketing authorization underpinning the reference medicinal product must be based on a complete dossier; a generic application referring to a generic dossier is not possible. Generic applicants may need to submit additional pre ‑clinical or clinical data if their product does not fall within the definition of a generic (*i.e.* , where there are differences in active substances, therapeutic indications, strength, pharmaceutical form or route of administration, in relation to the reference medicinal product, or where bioequivalence cannot be demonstrated through standard bioavailability studies). In these cases, bridging data is required to demonstrate that the differences do not affect the product’s relative safety and effectiveness inappropriately.

Pre ‑clinical and clinical data can be omitted and replaced with references to scientific literature if the product has been in well ‑established medicinal use in the European Union for at least 10 years. An existing marketing authorization holder may also give consent for a subsequent applicant to reference the pharmaceutical, pre ‑clinical and clinical data on file for the original product.

In the EEA, companies developing a new medicinal product must agree a Paediatric Investigation Plan (PIP) with the EMA and must conduct pediatric clinical trials in accordance with that PIP, unless a waiver applies, *e.g.* , because the relevant disease or condition occurs only in adults. The marketing authorization application for the product must include the results of pediatric clinical trials conducted in accordance with the PIP, unless a waiver applies, or a deferral has been granted, in which case the pediatric clinical trials must be completed at a later date.

Medicinal products may only be manufactured in the EEA, or imported into the EEA from another country, by the holder of a manufacturing authorization from the competent national authority. The product must have been manufactured in accordance with EU standards of GMP before it can be released onto the EEA market. Manufacturing facilities are subject to periodic inspections by the competent authorities for compliance with GMP.

The holders of marketing authorizations in the EEA are subject to various post ‑approval controls and requirements. These include the establishment of a pharmacovigilance system and reporting of adverse reactions. The regulatory authorities may impose specific obligations as a condition of the marketing authorization, such as additional safety monitoring, or the conduct of additional clinical trials or post ‑authorization safety studies. There are also specific rules governing advertising and promotion of medicinal products, including a requirement that all advertising and promotional activities for the product be consistent with the approved summary of product characteristics, and a prohibition on direct ‑to ‑consumer advertising of prescription medicines.

Other

Our operations and many of the products we manufacture or sell are subject to extensive regulation by numerous other governmental agencies, both within and outside the United States. In the United States, apart from the agencies discussed above, our facilities, operations, employees, products (their manufacture, sale, import and export) and services are regulated by Environmental Protection Agency, the Occupational Health & Safety Administration, the Department of Labor, Customs and Border Protection, the Department of Commerce, the Department of Treasury, the Department of Justice and others. Furthermore, because we supply products and services to healthcare providers that are reimbursed by federally funded programs such as Medicare, our activities are also subject to regulation by the Centers for Medicare and Medicaid Services and enforcement by the Office of the Inspector General within the Department of Health and Human Services. We are also required to report payments and other transfers of value to physicians and teaching hospitals, among others. State agencies also regulate our facilities, operations, employees, products and services within their respective states. Government agencies outside the United States also regulate public health, product registration, manufacturing, environmental conditions, labor, exports, imports and other aspects of our global operations.

Employees

As of December 31, 2015, we had 182 employees, with 95 in sales and marketing, 66 in research and development, clinical, regulatory and quality assurance, 11 in general and administrative, and 10 in manufacturing and distribution. We often supplement our research and development and clinical, regulatory and quality assurance departments with independent consultants on a project basis. We believe that our future success will depend in part on our continued ability to attract, hire and retain qualified personnel. None of our employees is represented by a labor union. We consider our relationship with our employees to be good.

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, free of charge, as soon as reasonably practicable after the electronic filing of these reports with, or furnishing of these reports to, the SEC. Any materials we file with the Securities and Exchange Commission (SEC) are available at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. Additional information about the operation of the Public Reference Room can also be obtained by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains a web site at www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including us.

ITEM 1A. RISK FACTORS

Our business faces significant risks and uncertainties. Certain important factors may have a material adverse effect on our business prospects, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in or incorporated by reference into this Annual Report on Form 10-K and our other public filings with the SEC. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

Risks Related to Our Business

We have incurred significant losses since inception and there can be no guarantee as to when, if ever, we may be able to achieve or sustain profitability.

Since inception in July 1998, we have incurred significant operating losses. For the years ended December 31, 2015, 2014 and 2013, we had net losses of $38.3 million, $14.1 million and $14.2 million, respectively. As of December 31, 2015, we had an accumulated deficit of approximately $196.6 million. Losses have resulted principally from costs incurred in our clinical trial, research and development programs and from our general and administrative expenses. Additionally , in 2015, we recorded a charge of $25.7 million incurred with the deconsolidation of the non -glaucoma

related assets of DOSE and elimination of the noncontrolling interest. To date, we have financed our operations primarily through the sale of equity securities, debt financing through a credit line and, more recently, sales of the *iStent* . We have devoted substantially all of our resources to the research and development of our products, the commercial launch of the *iStent* , the development of our proprietary sales network, and the assembly of a management team to build our business .

To implement our business strategies we need to, among other things, further grow our sales and marketing infrastructure to increase market acceptance of the *iStent* and any other products that receive FDA approval, fund ongoing research and development activities, expand our manufacturing capabilities, and obtain regulatory clearance or approval to commercialize our existing products in international markets or to commercialize those currently under development in the United States and internationally. As a result, we expect our expenses to increase significantly as we pursue these objectives. The extent of our future operating losses and the timing of profitability are highly uncertain, especially given our limited commercial history with the *iStent* , which makes forecasting our sales more difficult. We will need to generate significant additional net sales to achieve and maintain profitability, and even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time. Our failure to achieve or sustain profitability could have an adverse effect on the value of our common stock.

Substantially all of our net sales are generated from sales of the iStent, which has a limited commercial history, and we are completely dependent on its success. If the iStent or our other products under development fail to gain widespread market acceptance, our business will suffer.

Our primary sales ‑generating commercial product is the *iStent* , which we began selling in the United States in the third quarter of 2012. We rely heavily upon sales in the United States, which comprised 94.4% and 94.2% of our net sales for the years ended December 31, 2015 and 2014, respectively. We expect to continue to derive a significant portion of our net sales from sales of the *iStent* in the United States, even if we are successful in commercializing our *iStent* products outside the United States, or receive necessary approvals to commercialize the *iStent Inject, iStent Supra* and *iDose* . Accordingly, our ability to generate net sales is highly dependent on our ability to market and sell the *iStent* .

We have pioneered MIGS to revolutionize the traditional glaucoma treatment and management paradigm. The *iStent* is our first MIGS device and we are leveraging our platform technology to build a comprehensive and proprietary portfolio of micro ‑scale injectable therapies designed to address the complete range of glaucoma disease states and progression. MIGS and our MIGS devices may not gain sufficient market acceptance among eye care professionals, patients, healthcare payors and the medical community. There are a number of other available therapies marketed for the treatment of glaucoma, including medication therapies that are well established and are widely accepted by the medical community. Eye care professionals, patients, healthcare payors and the medical community may be slow or fail to adopt our products for a variety of reasons, including, among others:

- lack of experience with our products;
- lack of availability of adequate coverage and reimbursement for hospitals, ambulatory surgery centers and physicians;
- our inability to convince key opinion leaders to provide recommendations regarding our products, or to convince eye care professionals, patients and healthcare payors that our products are attractive alternatives to other products and treatment solutions;
- lack of evidence supporting cost benefits or cost ‑effectiveness of our products over existing alternatives;
- perception that our products are unproven, investigational or experimental;
- the price our products relative to competing treatment alternatives;
- liability risks generally associated with the use of new products and procedures; and
- training required to use new products.

If we are not successful in increasing market acceptance of our products, overall utilization of our products may fall below targeted levels and our future net sales will be adversely impacted. Because of the numerous risks and

uncertainties associated with our commercialization efforts, we are unable to predict the extent to which we will continue to generate net sales from our products or the timing for when or the extent to which we will become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis.

We have limited experience marketing and selling the iStent. If we are unable to leverage our existing direct sal es and marketing infrastructure to increase market acceptance of our products, we may not achieve sufficient net sales growth to become profitable .

We began marketing the *iStent* in the United States after receiving FDA approval in 2012. As a result, we have limited experience marketing and selling the *iStent* . Our operating results are directly dependent upon the sales and marketing efforts of our employees. If our direct sales representatives fail to adequately promote, market and sell our products, our sales may suffer.

In order to generate increased sales, we will need to leverage our existing direct sales organization, including targeted expansion to ensure sufficient geographic coverage . As a result, our future success will depend largely on our ability to continue to train, retain and motivate skilled regional sales managers and direct sales representatives with significant technical knowledge of MIGS and the *iStent* . Because of the competition for their services, we cannot assure you we will be able to retain our direct sales representatives on favorable or commercially reasonable terms, if at all. Failure to retain qualified sales representatives would prevent us from expanding our business and generating sales.

If we are unable to leverage our competitive sales and marketing infrastructure , we may not be able to effectively commercialize our products, which would adversely affect our business, results of oper ations and financial condition.

We face manufacturing risks that may adversely affect our ability to manufacture products and could reduce our gross margins and negatively affect our operating results.

Our business strategy depends on our ability to manufacture our current and proposed products in sufficient quantities and on a timely basis so as to meet customer demand, while adhering to product quality standards, complying with regulatory requirements and managing manufacturing costs. We currently have a single manufacturing facility located at our corporate headquarters in Laguna Hills, California, where we manufacture, inspect, package, release and ship all final products. If this facility suffers a crippling event, or a force majeure event, this could materially impact our ability to operate.

We will require additional space as our business expands. Accordingly, in June 2015 we entered into a sublease for an approximately 37,700 square foot facility located in San Clemente, California effective September 1, 2015, as well as a five -year lease for these premises that takes effect January 1, 2017 upon expiration of the sublease. We plan for this facility to serve as our headquarters beginning sometime in 2016. The new facility will require regulatory approvals. In addition, it will be costly and time -consuming to expand our operations and recruit necessary additional personnel. If we are unable to expand our manufacturing facility in compliance with regulatory requirements or to hire additional necessary manufacturing personnel, we may encounter delays or additional costs in achieving our research, development and commercialization objectives, including in obtaining regulatory approvals of our product candidates and meeting customer demand, which could materially damage our business and financial position.

We are also subject to numerous other risks relating to our manufacturing capabilities, including:

- quality and reliability of product components that we source from third - party suppliers, including the risk of receiving contaminated heparin or sourcing quality heparin in quantities sufficient to coat our products;
- our inability to secure product components in a timely manner, in sufficient quantities or on commercially reasonable terms;
- our inability to maintain compliance with quality system requirements;
- our failure to increase production capacity or volumes to meet demand;
- our inability to design or modify production processes to enable us to produce efficiently future products or implement changes in current products in response to design or regulatory requirements; and

- difficulty identifying and qualifying alternative suppliers for components in a timely manner.

These risks are likely to be exacerbated by our limited experience with our current products and manufacturing processes. As demand for our products increases, we will have to invest additional resources to purchase components, hire and train employees and enhance our manufacturing processes. If we fail to increase our production capacity efficiently, our sales may not increase in line with our expectations and our operating margins could fluctuate or decline. In addition, although we expect some of our products in development to share product features and components with the *iStent* , the manufacture of these products may require the modification of our current production processes or unique production processes, the hiring of specialized employees, the identification of new suppliers for specific components or the development of new manufacturing technologies. It may not be possible for us to manufacture these products at a cost or in quantities sufficient to make these products commercially viable or to maintain current operating margins.

We depend on a limited number of third -party suppliers for certain components, and the loss of any of these suppliers, or their inability to provide us with an adequate supply of materials, could harm our business.

We rely on a limited number of third -party suppliers to supply components for the *iStent* , the *iStent Inject* and its unique injector system and our other pipeline products. Other than agreements with key suppliers, we generally do not enter into long -term supply agreements with our suppliers, and we order most components on a purchase order basis. In some cases, we have a sole supplier or a limited number of suppliers. For example, we rely on one machining company to manufacture the titanium *iStent* implant and one pharmaceutical supplier for the heparin used in the *iStent's* heparin coating. While we believe that there are at least several other vendors that could supply the titanium implant, and other pharmaceutical vendors that could supply heparin, we have not yet qualified any of these vendors, which could cause delay, thereby impairing our ability to meet the demand of our customers. Although we maintain inventory to mitigate supply interruptions, we are nevertheless exposed to risks, including limited control over costs, availability, quality and delivery schedules.

Moreover, due to the recent commercialization of the *iStent* and the limited amount of sales to date, we do not have long -standing relationships with our suppliers and may not be able to convince suppliers to continue to make components available to us unless the volume of our orders continues to increase. As a result, there is a risk that certain components could be discontinued and no longer available to us.

We have in the past been, and we may in the future be, required to make significant “last time” purchases of components that are being discontinued by the supplier to ensure supply continuity. In addition, given our limited experience with these suppliers, it may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. If any one or more of our suppliers cease to provide us with sufficient quantities of components 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 quality control standards and regulatory requirements, we cannot quickly engage additional or replacement suppliers for some of our critical components. 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 further delay.

Failure of any of our suppliers to deliver products at the level our business requires would limit our ability to meet our sales commitments, which could harm our reputation and could have a material adverse effect on our business. We may also have difficulty obtaining similar components from other suppliers that are acceptable to the FDA or other regulatory agencies, and the failure of our suppliers to comply with strictly enforced regulatory requirements could expose us to regulatory action including warning letters, product recalls, termination of distribution, product seizures or civil penalties. It could also require us to cease using the components, seek alternative components or technologies and modify our products to incorporate alternative components or technologies, which could result in a requirement to seek additional regulatory approvals. Our suppliers may also encounter financial or other hardships unrelated to our demand for components, which could inhibit their ability to fulfill our orders and meet our requirements. Any disruption of this nature or increased expense could harm our commercialization efforts and adversely affect our operating results.

In addition, we rely on our suppliers to supply us with components that comply with regulatory requirements and quality control standards, and meet agreed upon specifications, all at acceptable costs and on a timely basis. Although we expect our third -party suppliers to act consistent with such standards, we do not control our suppliers, as

they operate and oversee their own businesses. There is a risk that our suppliers will not always act consistent with our best interests, and may not always supply components that meet our needs. Accordingly, if we fail to obtain sufficient quantities of high -quality components to meet demand for our products on a timely basis, we could lose customer orders, our reputation may be harmed and our business could suffer.

We currently operate primarily at a facility in a single location and any crippling accident, force majeure event or disruption at this facility could materially affect our ability to operate and produce saleable products and could shut down our manufacturing capacity for an extended period.

Our principal office is currently located in one building in Laguna Hills, California. Following the relocation of our corporate headquarters to the facility located in San Clemente, California, we will continue to operate primarily in a single location. Thus, substantially all of our operations are and will continue to be conducted at a single location, including our manufacturing processes, research and development activities, customer and technical support, and management and administrative functions. In addition, substantially all of our inventory of component supplies and finished goods is and will be held at a single location. Despite our efforts to safeguard our facilities, including acquiring insurance, adopting environmental health and safety protocols and utilizing off -site storage of computer data, vandalism, terrorism or a natural or other disaster, such as an earthquake, fire or flood, could damage or destroy our manufacturing equipment or our inventory of component supplies or finished goods, cause substantial delays in our operations, result in the loss of key information, and cause us to incur additional expenses, including relocation expenses. Our insurance may not cover our losses in any particular case. In addition, regardless of the level of insurance coverage, damage to our facilities may have a material adverse effect on our business, financial condition and operating results

Failure to secure and maintain adequate coverage or reimbursement by third -party payors in the United States for procedures using the iStent or our other products in development, or changes in current coverage or reimbursement, could materially impact our net sales and future growth.

We currently derive nearly all our net sales from sales of the *iStent* in the United States and expect this to continue for the next several years. Hospitals and ambulatory surgery centers that purchase the *iStent* typically bill various third -party payors, including Medicare, Medicaid, private commercial insurance companies, health maintenance organizations and other healthcare -related organizations, to cover all or a portion of the costs and fees associated with the MIGS procedures in which the *iStent* is used and bill patients for any applicable deductibles or co -payments. Access to adequate coverage and reimbursement for the procedures using the *iStent* (and our other products in development) by third -party payors is essential to the acceptance of our products by our customers.

Because there is generally no separate reimbursement for medical devices and other supplies used in such procedures, including the *iStent* , the additional cost associated with the use of our *iStent* device could impact the profit margin of the hospital or surgery center where the cataract surgery is performed if the incremental facility fee payment is not sufficient. Some of our target customers may be unwilling to adopt our *iStent* in light of the additional associated cost. Further, any decline in the amount payors are willing to reimburse our customers for MIGS procedures could make it difficult for existing customers to continue using, or new customers to adopt, our *iStent* devices and could create additional pricing pressure for us. If we were forced to lower the price we charge for our products, our gross margins would decrease, which would adversely affect our ability to invest in and grow our business.

Third -party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for medical device products and services exists among third -party payors. Therefore, coverage and reimbursement for medical device products and services can differ significantly from payor to payor. In addition, payors continually review new technologies for possible coverage and can, without notice, deny coverage for these new products and procedures. As a result, the coverage determination process is often a time -consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained, or maintained if obtained.

Many third -party payors in the United States model their coverage policies and payment amounts after those determined by the CMS, the federal agency responsible for administering the Medicare program. CMS relies on a network of MACs, which process nearly 4.9 million Medicare claims each day and disburse more than $365 billion annually, to develop coverage policies when no national coverage determination exists for a procedure. Because there

currently is no Medicare national coverage determination for procedures using our *iStent* devices, we are required to provide scientific and clinical support for the use of the *iStent* (including the *iStent Inject* device and *iStent Supra* device, if approved) to each MAC separately, with no assurance that coverage and adequate reimbursement will be obtained. Although all MACs currently provide coverage and reimbursement for the MIGS procedure using the *iStent* , difficulties in processing reimbursement or regional differences in the reimbursement amount for the physician professional services could negatively impact further *iStent* penetration or usage by customers. These differences in MAC reimbursement could also negatively impact the amount paid by private commercial insurance companies, further negatively affecting customer penetration or usage.

Third ‑party payors, including CMS, regularly assess and propose changes to their coverage and reimbursement policies. Changes in these current policies impact the profit margin of the hospital or surgery center where the surgery is performed and increase costs to customers. For example, beginning in 2016, Medicare will make a single, comprehensive payment for combination *iStent* insertion and cataract procedures performed in hospital outpatient departments, or HOPDs, eliminating the separate payments that were available for the procedures in prior years and reducing the total reimbursement amount for the combination procedure in the HOPD. Further, any decline in the amount payors are willing to reimburse our customers for MIGS procedures could make it difficult for existing customers to continue using, or new customers to adopt, our *iStent* devices and could create additional pricing pressure for us. If we were forced to lower the price we charge for our products, our gross margins would decrease, which would adversely affect our ability to invest in and grow our business.

Some third ‑party payors in the United States, including Medicaid and TRICARE and certain commercial payors, have developed policies that deny coverage for the MIGS procedure using the *iStent* . To support changes in these policies, we may need to conduct prospective, randomized controlled clinical trials and present data from such trials to these payors to demonstrate the medical necessity or cost ‑effectiveness of the *iStent* . There can be no assurance that coverage for our products will be expanded. In addition, those private payors that do not follow the Medicare guidelines may adopt different coverage and reimbursement policies for MIGS procedures performed with the *iStent* , though we cannot predict whether coverage will be sufficient or if there will be coverage at all. Failure to obtain favorable payor policies could have a material adverse effect on our business and operations.

We believe that Medicare coverage and existing coverage by third ‑party payors represents approximately 90% of our target patient population. U.S. third ‑party payors representing approximately 80% of individuals covered by commercial insurance currently reimburse the *iStent* procedure. While we anticipate gaining coverage and reimbursement from additional third ‑party payors, we cannot guarantee that we will be successful or that coverage and reimbursement will be at levels that support continued penetration and usage by our customers. Moreover, compliance with the administrative procedures and requirements of third ‑party payors may result in delays in processing approvals by those third ‑party payors for customers to obtain coverage and reimbursement for procedures using the *iStent* . Failure to secure or maintain adequate coverage or reimbursement for procedures using the *iStent* by third ‑party payors, or delays in processing approvals by those payors, could result in the cancellations of procedures to insert the *iStent* in combination with cataract surgery, resulting in the loss of net sales from these procedures. If these issues remain unresolved, they could have a material adverse effect on our business, financial condition and operating results.

In addition, although we have obtained temporary Category III Current Procedural Terminology codes for the MIGS procedures associated with the insertion of our *iStent* products, there is no guarantee that these billing codes or the payment amounts associated with such codes will not change in the future. Category III codes expire five years after the date they become effective. Prior to expiration, there are two options: submit an application to convert to a permanent Category I code; or submit an application for a five year extension of Category III status. If we are unable to maintain our existing codes or obtain new permanent Category I codes for procedures using our *iStent* products, or obtain new reimbursement codes for our other products in development, we will be subject to significant pricing pressure, which could harm our business, results of operations, financial condition and prospects.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Adequate coverage and reimbursement from governmental and commercial payors are critical to new product acceptance. Third ‑party coverage and reimbursement for our products or any of our product

candidates for which we may receive regulatory approval may not be available or adequate in either the United States or international markets.

The medical device industry is highly competitive and subject to rapid technological change. Many of our current and potential competitors (including MIGS competitors) are large public companies or divisions of publicly traded companies and have several competitive advantages. If our competitors are better able to develop and market products that are safer, more effective, less costly or otherwise more attractive than the iStent or any new products that we may develop, our commercial opportunity may be reduced or eliminated .

The medical device industry is highly competitive and subject to rapid and profound technological change. Our success depends, in part, upon our ability to maintain a competitive position in the development of MIGS products.

We compete primarily with the use of medication therapy for treating glaucoma and with manufacturers of medical devices used in surgical therapy procedures for treating glaucoma, including Alcon, Inc. (which has entered into a definitive agreement to acquire Transcend Medical, Inc., a MIGS competitor), Abbott Medical Optics Inc., Allergan plc (which has entered into a definitive merger agreement with Pfizer, Inc., pursuant to which the two companies intend to combine), STAAR Surgical Company, Lumenis Ltd., NeoMedix,Inc. and Ellex Medical Lasers Limited. Alcon, Inc. and Abbott Medical Optics Inc. are the leading manufacturers of aqueous shunts, and Alcon, Inc. also markets the EX - PRESS Glaucoma Filtration Device and, upon its completion of the Transcend Medical, Inc. acquisition, will be a manufacturer of a MIGS device. Lumenis Ltd. is a leading manufacturer of selective laser trabeculoplasty equipment. Neomedix, Inc. markets an electrosurgical device, and Ellex Medical Lasers Limited markets a canaloplasty device that some physicians employ to lower intraocular pressure in glaucoma.

Our competitors, medical companies, academic and research institutions or others could develop new drugs, therapies, medical devices or surgical procedures to treat glaucoma that could render our products obsolete. For example, we are aware of several companies, including Transcend Medical, Inc., AqueSys, Inc., InnFocus Inc. and Ivantis Inc. that are conducting FDA -approved IDE clinical trials or have filed for regulatory approval of MIGS devices. These products or other products that may be developed could demonstrate better safety or effectiveness, clinical results, ease of use or lower costs than our *iStent* or other products under development. If approved for marketing, these devices may compete directly with the *iStent* and our products under development. If any of these alternative technologies gain market acceptance, this may reduce demand for our primary product, the *iStent* , as well as for our products in development. Demand for the *iStent* or our future products may decline if such a product or technology were introduced, and our business may be harmed .

Many of our current and potential competitors (including MIGS competitors) are large public companies or divisions of publicly -traded companies and have several competitive advantages, including :

- greater financial and human resources for product development, sales and marketing and patent litigation;
- significantly greater name recognition;
- longer operating histories;
- established relationships with healthcare professionals, customers and third -party payors;
- additional lines of products, and the ability to offer rebates or bundle products to offer higher discounts or incentives;
- more established sales and marketing programs and distribution networks; and
- greater experience in conducting research and development, manufacturing, clinical trials, preparing regulatory submissions and obtaining regulatory clearance or approval for drug and device products and marketing approved products.

Recently, Aqu eS ys, Inc. was acquired by Allergan plc, a publicly -traded company, and Allergan and Pfizer, Inc. have entered into a definitive merger agreement, pursuant to which the two companies intend to combine. Similarly, Alcon, Inc. (a division of Novartis International AG, which is a publicly traded multinational pharmaceutical company based in Basel, Switzerland) has entered into a definitive agreement to acquire Transcend Medical, Inc. As a result of

these transactions and in the event other companies that are developing MIGS devices are acquired by larger companies, we could be competing directly against other MIGS competitors that could have the competitive advantages identified above .

The training required for surgeons to use the iStent could reduce the market acceptance of our products.

As with any new method or technique, ophthalmic surgeons must undergo a thorough training program before they are qualified to perform the *iStent* procedure. Surgeons could experience difficulty with the technique necessary to successfully insert the *iStent* , intraoperative gonioscopy, and not achieve the technical competency necessary to be qualified to insert our stents. Also, even after successfully completing the training program, the physicians could experience difficulty inserting our products and cease utilizing them or limit their use significantly in practice.

We could also experience difficulty meeting expected levels of ophthalmic surgeons who complete our training program. This could happen due to less demand than expected, the length of time necessary to train each surgeon being longer than expected, the capacity of our sales representatives to train surgeons being less than anticipated, or if we are unable to sufficiently increase our sales organization. All of these events would lead to fewer trained ophthalmic surgeons qualified to insert the *iStent* , which could negatively impact our operating and financial results.

Ophthalmic surgeons not completing the iStent training program may nevertheless elect to perform iStent procedures and experience inferior clinical outcomes.

Although our sales representatives manage the training program for ophthalmic surgeons to become qualified to insert the *iStent* in combination with cataract surgery, once training is completed the surgeon and/or surgical facility that the surgeon utilizes are cleared to order and maintain an *iStent* supply. There is a risk that untrained or unqualified ophthalmic surgeons could gain access to *iStent* devices from a facility's inventory and conduct *iStent* procedures without having received qualified status from us. If performing *iStent* procedures by unqualified ophthalmic surgeons were to become pervasive, this could raise the risk of complications and inferior clinical outcomes, which could result in negative patient experiences or experiences being published and damaging our reputation and that of the *iStent* . This could result in lower penetration and utilization by ophthalmic surgeons and could have a material adverse effect on our net sales growth, expected operating results and financial condition.

The safety and efficacy of the iStent and our other products are not yet supported by long‑term clinical data in large numbers of patients. 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.

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 longer‑term patient studies or clinical experience indicate that treatment with our products is less effective, less efficient or less safe than our current data suggest, our sales would be harmed, and we could be subject to significant liability. Further, unsatisfactory patient outcomes or patient injury could cause negative publicity for our products, particularly in the early phases of product introduction. In addition, physicians may be slow to adopt our products if they perceive liability risks arising from their use. 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.

Product liability suits brought against us could cause us to incur substantial liabilities, limit sales of our existing products and limit commercialization of any products that we may develop.

If our product offerings, including the *iStent* , are defectively designed or manufactured, contain defective components, or are used or deployed improperly, or if someone claims any of the foregoing, whether or not such claims are meritorious, we may become subject to substantial and costly litigation. Any product liability claims brought against us, with or without merit, could divert management's attention from our business, be expensive to defend, result in sizable damage awards against us, damage our reputation, increase our product liability insurance rates, prevent us from securing continuing coverage, or prevent or interfere with commercialization of our products. In addition, we may not have sufficient insurance coverage for all future claims. Product liability claims brought against us in excess of our insurance coverage would likely be paid out of cash reserves, harming our financial condition and results of operations.

Operating results could be unpredictable and may fluctuate significantly from quarter to quarter, which could adversely affect our business, financial condition, results of operations and the trading price of our common stock.

Because we have limited experience marketing and selling the *iSten* t, our net sales from the sale of the *iStent* may experience volatility due to a number of factors, many of which are beyond our control, including:

- our ability to drive increased sales of our products;
- our ability to establish and maintain an effective and dedicated sales organization;
- fluctuations in the demand for our products;
- pricing pressure applicable to our products, including adverse third ‑party coverage and reimbursement outcomes;
- results of clinical research and trials on our products;
- fluctuations in the number of cataract procedures performed by our customers, which could decrease significantly during holiday seasons and summer months, when significant numbers of physicians and patients may schedule vacations;
- timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors;
- deferrals of customer orders in anticipation of the introduction of new products or product enhancements by us;
- regulatory approvals and legislative changes affecting the products we may offer or those of our competitors;
- interruption in the manufacturing or distribution of our products;
- the ability of our suppliers to timely provide us with an adequate supply of product components;
- the effect of competing technological, industry and market developments;
- changes in our ability to obtain regulatory clearance or approval for our products or to obtain or maintain our CE Certificates of Conformity for our products;
- variances in the sales terms, timing or volume of customer orders from period to period;
- the length of our sales cycle, which varies and may be unpredictable; and
- our ability to expand the geographic reach of our sales and marketing efforts.

As a result, you should not rely 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 are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Our long ‑term growth depends on our ability to develop and commercialize additional products using our iStent technologies. If we are not able to commercialize products in development in a timely manner, our products may become obsolete over time, customers may not buy our products and our net sales and profitability may decline.

Demand for our products may change in ways we may not anticipate due to:

- changing coverage and reimbursement, coding and payments;
- changing customer needs;
- the introduction of new products and technologies;

- evolving surgical practices;
- evolving industry standards; and
- other unforeseen reasons.

As a result, it is important that we continue to build a more complete product offering using our *iStent* technologies. Developing additional products is expensive and time ‑consuming, and could divert management's attention away from expanding acceptance of the *iStent* and harm our business. Even if we are successful in developing additional products, including those currently in development, the success of our new product offerings, if any, will depend on several factors, including our ability to:

- properly identify and anticipate customer needs;
- commercialize new products in a cost ‑effective and timely manner;
- manufacture and deliver products in sufficient volumes on time;
- obtain regulatory approval for new products;
- receive adequate coverage and reimbursement for procedures performed with our products;
- differentiate our offerings from competitors' offerings;
- achieve positive clinical outcomes;
- satisfy the increased demands from healthcare payors, providers and patients for lower ‑cost procedures;
- innovate and develop new materials, product designs and surgical techniques; and
- provide adequate medical and consumer education relating to new products and attract key ophthalmologists and other eye care professionals to advocate these new products.

Moreover, we will need to make a substantial investment in research and development before we can determine the commercial viability of any innovations, and we may not have the financial resources required to fund such research and development. In addition, even if we are able to successfully develop product enhancements or new products, these enhancements or new products may not produce net sales in excess of the costs of development, or they may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying superior technologies or features.

Research programs to identify new products will require substantial technical, financial and human resources, whether or not any such products are ultimately identified. We may determine that one or more of our pre ‑clinical programs does not have sufficient potential to warrant the allocation of such resources. Our research programs may initially show promise in identifying potential products, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology used may not be successful in identifying potential products;
- competitors may develop alternatives that render our future products, if any, obsolete;
- our products may not be deployed safely or effectively;
- our future products, if any, may, on further study, be shown to have harmful side effects or other characteristics that indicate they are unlikely to be effective;
- our clinical trials may not be successful; and
- we may not receive regulatory approval.

If we fail to manage our anticipated growth effectively, our business could suffer.

Since commercial launch of the *iStent* in July 2012, we have seen significant period ‑to ‑period growth in our business. We anticipate that this rapid growth will continue in the near term as the *iStent* continues to gain market acceptance. Not only do we expect this growth to continue, but we must continue to grow in order to meet our business and financial objectives. However, continued growth may create numerous challenges, including:

- new and increased responsibilities for our management team;
- increased pressure on our operating , financial and reporting systems;
- increased pressure from our competitors;
- increased pressure to anticipate and satisfy market demand;
- additional manufacturing capacity requirements;
- strain on our ability to source a larger supply of components that meet our required specifications on a timely basis;
- management of an increasing number of relationships with our customers, suppliers and other third parties; and
- the need to hire, train and manage additional qualified personnel.

If we fail to manage any of the above challenges effectively, our business may be harmed.

Our future growth depends on our ability to retain members of our senior management and other key employees. 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 as well as certain key employees. For example, our chief executive officer, as well as other key members of our senior management, have experience successfully developing novel technologies and scaling early ‑stage medical device companies to achieve profitability. Our success will depend on our ability to retain our current management and key employees, and to attract and retain qualified personnel in the future. Competition for senior management and key employees in our industry is intense and we cannot guarantee that we will be able to retain our personnel or attract new, qualified personnel. The loss of services of certain members of our senior management or key employees could prevent or delay the implementation and completion of our strategic objectives, or divert management's attention to seeking qualified replacements. Each member of senior management as well as our key employees may terminate employment without notice and without cause or good reason. The members of our senior management are not subject to non ‑competition agreements. Accordingly, the adverse effect resulting from the loss of certain members of senior management could be compounded by our inability to prevent them from competing with us.

In addition to competing for market share for our products, we also compete against these companies for personnel, including qualified sales representatives that are necessary to grow our business. Also, we compete with universities and research institutions for scientific and clinical personnel that are important to our research and development efforts.

We also rely on consultants and advisors in our research, operations, clinical and commercial efforts to implement our business strategies. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

Our strategic plan requires us to continue growing our sales, marketing, clinical and operational infrastructure in order to generate, and meet, the demand for our products. If we fail to retain or attract these key personnel, we could fail to take advantage of the market for our *iStent* technologies and our business, financial condition and operating results could be adversely affected.

Our iDose implant will be regulated as a drug and be subject to a different regulatory approval process than our other products in development. iDose is in early stages of development and may never be commercialized.

As a drug delivery implant, the *iDose* will be subject to a regulatory approval process similar to that for pharmaceuticals. This process is often a more lengthy and complex process than obtaining regulatory approval as a medical device. The future success of our *iDose* product candidate depends on our ability to complete clinical trials, and will require significant development activities, clinical trials, regulatory approvals, and substantial additional investment.

This development program may not lead to a commercially viable product for several reasons. For example, we may fail to demonstrate safety and efficacy in pre-clinical tests or clinical trials, or we may have inadequate financial or other resources to pursue drug development efforts. From time to time, we may establish and announce certain development goals for our *iDose* product candidate; however, it is difficult to predict accurately if and when we will achieve these goals. We may be unsuccessful in advancing this drug delivery implant into clinical testing or in obtaining FDA approval, and our long-term business prospects could be harmed.

Our business requires substantial capital and operating expenditures to operate and grow.

Although we raised net proceeds of approximately $113.6 million from our IPO and generate net sales from our first FDA-approved product, the *iStent* , we may nevertheless need to raise substantial additional capital in the future to:

- expand our sales and marketing organization in the United States and internationally;
- fund our operations, clinical trials and commercialization efforts for new products, if any such products receive regulatory approval for commercial sale;
- scale-up our manufacturing operations;
- pursue additional research and development;
- enforce or defend, in litigation or otherwise, our patent or other intellectual property rights against infringement, misappropriation or other violation by third parties or any claims that we infringe or have otherwise violated third-party patent or other intellectual property rights; and
- acquire companies or in-license products or intellectual property.

We believe that the net proceeds from our IPO, together with our existing cash, cash equivalents, short-term investment balances and interest we earn on these balances and cash generated from sales of our *iStent products* will be sufficient to meet our anticipated cash requirements for the next 12 months. However, our future funding requirements will depend on many factors, including:

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- the cost of filing and prosecuting patent applications and defending and enforcing our patent and other intellectual property rights;
- the cost of asserting or defending, in litigation or otherwise, our patent or other intellectual property rights against infringement, misappropriation or other violation by third parties or any claims that we infringe or have otherwise violated third-party patent or other intellectual property rights;
- the terms and timing of any collaborative, licensing and other arrangements that we may establish;
- the cost and timing of regulatory approvals;
- the cost and timing of establishing sales, marketing and distribution capabilities;
- the cost of establishing clinical and commercial supplies of our products and any products that we may develop;
- the effect of competing technological and market developments;

- licensing technologies for future development; and
- the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

If we raise additional funds through further issuances of equity or issuances of convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences and privileges superior to those of holders of our common stock. Any debt financing obtained by us in the future would likely be senior to our common stock, would likely cause us to incur interest expense, and could involve restrictive covenants relating to our capital raising activities and other financial and operational matters, which may increase our expenses and make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. We may also be required to secure any such debt obligations with some or all of our assets.

We cannot assure you that we will be able to obtain additional financing on terms favorable to us, if at all. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, or if we expend capital on projects that are not successful, our ability to continue to support our business growth and to respond to business challenges could be significantly limited, or we may even have to scale back our operations.

We may enter into acquisitions, collaborations, in -licensing agreements, joint ventures, alliances or partnerships with third parties that fail to result in a commercial product or net sales.

We do not have any current commitments to enter into any acquisitions, collaborations, in -licensing agreements, joint ventures, alliances or partnerships. We may in the future choose to undertake one or more of these transactions in order to retain our competitive position within the marketplace or to expand into new markets. However, we cannot assure you that we would be able to successfully complete any acquisition we choose to pursue, or that we would be able to successfully integrate any acquired business, product or technology in a cost -effective and non -disruptive manner. If we were unable to integrate any acquired businesses, products or technologies effectively, our business would likely suffer.

Failure to protect our information technology infrastructure against cyber-based attacks, network security breaches, service interruptions or data corruption could materially disrupt our operations and adversely affect our business and operating results .

The efficient operation of our business depends on our information technology systems. 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, 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, cyber-based attacks, attacks by computer viruses or hackers, power losses, computer system or data network failures , security breaches and data corruption. In addition, a variety 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 of either our or our service providers' information technology could disrupt our entire operation or result in decreased sales, increased overhead costs and product shortages, all of which could have a material adverse effect on our reputation, business, financial condition and operating results.

Planned expansion into new markets outside of the United States will subject us to additional business and regulatory risks, and there can be no assurance that our products will be accepted in those markets.

Engaging in international business inherently involves a number of other difficulties and risks, including:

- competition from established companies, many of which are well -positioned within their local markets with longer operating histories, more recognizable names and better established distribution networks;
- the availability and level of coverage and reimbursement within prevailing foreign healthcare payment systems and the ability of patients to elect to privately pay for the *iStent* and our other products;

- difficulties in enforcing intellectual property rights;
- pricing pressure;
- required compliance with existing and changing foreign regulatory requirements and laws;
- laws and business practices favoring local companies;
- longer sales and payment cycles;
- difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- political and economic instability;
- foreign currency risks that could adversely affect our financial results;
- potentially adverse tax consequences, tariffs and other trade barriers;
- exposure to liabilities under anti -corruption and anti -money laundering laws, including the U.S. Foreign Corrupt Practices Act, and similar laws and regulations in other jurisdictions;
- international terrorism and anti -American sentiment;
- difficulties and costs associated with staffing and managing foreign operations; and
- export restrictions and controls relating to technology.

If we or our suppliers are unable to address these international risks, we may fail to establish and maintain an international presence, and our business, financial condition and results of operations could suffer.

We cannot be certain that our net operating loss tax carryforwards will be available t o offset future taxable income.

As of December 31, 2015, we had net operating loss carryforwards of approximately $118. 0 million for U.S. federal income tax purposes and approximately $98.0 million of net operating loss carryforwards for state income tax purposes. The federal and state net operating loss carryforwards begin to expire in 2018 and 2016, respectively. At December 31, 2015, we had federal and state research and development carryforwards of $4.6 million and $5.1 million, respectively, which begin to expire in 202 1 for federal purposes and carry over indefinitely for state purposes. We have recorded a full valuation allowance against these tax attributes because we believe that uncertainty exists with respect to the future realization of the tax attributes as well as with respect to the amount of the tax attributes that will be available in future periods. To the extent available, we intend to use these net operating loss carryforwards to offset future taxable income associated with our operations. There can be no assurance that we will generate sufficient taxable income in the carryforward period to utilize any remaining net operating loss carryforwards before they expire .

In addition, Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, contains rules that limit for U.S. federal income tax purposes the ability of a corporation that undergoes an “ownership change” to utilize its net operating losses (and certain other tax attributes) existing as of the date of such ownership change. Under these rules, a corporation is treated as having had an “ownership change” if there is more than a 50% increase in stock ownership by one or more “five percent shareholders,” within the meaning of Section 382 of the Code, during a rolling three -year period. We believe a portion of our existing net operating losses are subject to limitations arising from previous ownership changes, and if we undergo an ownership change, our ability to utilize our net operating losses to offset future taxable income could be further limited, which could have a negative effect on our liquidity. For these reasons, we may not be able to utilize a material portion of our net operating losses, even if we attain profitability.

Risks Related to the Regulatory Environment

We and our suppliers are subject to extensive federal and state regulation, and if we fail to comply with applicable regulations, we could suffer severe criminal or civil sanctions or be required to make significant changes to our operations that could adversely affect our business, financial condition and operating results.

The *iStent* is classified as a medical device. As a result, we are subject to extensive government regulation in the United States by the FDA and state regulatory authorities and by foreign regulatory authorities in the countries in which we conduct business. These regulations relate to, among other things, research and development, design, testing, clinical trials, manufacturing, clearance or approval, environmental controls, safety and efficacy, labeling, advertising, promotion, pricing, recordkeeping, reporting, import and export, post -approval studies and the sale and distribution of the *iStent* and our other products in development.

In the United States, before we can market a new medical device, or a new use of, new claim for, or significant modification to, an existing product, we must first receive either clearance under Section 510(k) of the FDCA or approval of a PMA application from the FDA, unless an exemption applies. The process of obtaining PMA approval, which was required for the *iStent* , is much more costly and uncertain than the 510(k) clearance process. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, in order to clear the proposed device for marketing. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence. In the PMA approval process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre -clinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices for which the 510(k) process cannot be used and that are deemed to pose the greatest risk.

Modifications to products that are approved through a PMA application generally need FDA approval. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k). The FDA's 510(k) clearance process usually takes from three to 12 months, but may last longer. The process of obtaining a PMA generally takes from one to three years, or even longer, from the time the PMA is submitted to the FDA until an approval is obtained. Any delay or failure to obtain necessary regulatory approvals would have a material adverse effect on our business, financial condition and prospects.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are safe or effective for their intended uses;
- the disagreement of the FDA or the applicable foreign regulatory body with the design or implementation of our clinical trials or the interpretation of data from pre -clinical studies or clinical trials;
- serious and unexpected adverse device effects experienced by participants in our clinical trials;
- the data from our pre -clinical studies and clinical trials may be insufficient to support clearance or approval, where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the manufacturing process or facilities we use may not meet applicable requirements; and
- the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug products is also subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, which regulations differ from country to country. We are not permitted to market any drug product

candidate in the United States until we receive FDA approval of a NDA or other appropriate drug product application. Prior to submitting a marketing application, human clinical studies are required. In order for clinical studies of a new drug to commence in the United States, an IND application must be filed with the FDA; similar notifications are required in other countries. Informed consent also must be obtained from study participants. In general, studies may begin in the United States without specific approval by the FDA after a 30 -day review period has passed. However, the FDA may prevent studies from moving forward, and may suspend or terminate studies once initiated. Studies are also subject to review by an independent IRB responsible for overseeing studies at particular sites and protecting human research study subjects. An IRB may prevent a study from beginning or suspend or terminate a study once initiated.

The FDA or other applicable foreign regulatory bodies can delay, limit or deny approval of a drug candidate for many reasons, including, but not limited to, the following:

- our inability to demonstrate to the satisfaction of the FDA or the applicable foreign regulatory body that the drug candidate is safe and effective for the requested indication;
- the FDA's or the applicable foreign regulatory body's disagreement with design or implementation of our clinical trials or the interpretation of data from preclinical studies or clinical trials;
- serious and unexpected drug -related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- our inability to demonstrate that the clinical and other benefits of the drug candidate outweigh any safety or other perceived risks;
- the FDA's or the applicable foreign regulatory body's requirement for additional preclinical or clinical studies;
- the FDA's or the applicable foreign regulatory body's non -approval of the drug candidate's chemistry, manufacturing or controls or labeling;
- the FDA's or the applicable foreign regulatory body's failure to approve the manufacturing processes or facilities of third -party manufacturers; or
- the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for approval.

Further, we are subject to laws directed at preventing fraud and abuse, which subject our marketing, training and other practices to government scrutiny. To ensure compliance with Medicare, Medicaid and other regulations, government agencies or their contractors often conduct routine audits and request customer records and other documents to support claims submitted for payment of services rendered. Government agencies or their contractors also periodically open investigations and obtain information from healthcare providers. Violations of federal and state regulations can result in severe criminal, civil and administrative penalties and sanctions, including debarment, suspension or exclusion from Medicare, Medicaid and other government reimbursement programs, any of which would have a material adverse effect on our business.

Legislative or regulatory reform of the healthcare system may affect our ability to sell our products profitably .

In the United States and in certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the regulatory and healthcare systems in ways that could impact our ability to sell our products profitably, if at all. In the United States 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.

For example, in 2011, the FDA announced a Plan of Action to modernize and improve the FDA's premarket review of medical devices, and has implemented, and continues to implement, reforms intended to improve the timeliness and predictability of the premarket review process. In addition, as part of the Food and Drug Administration Safety and Innovation Act of 2012, Congress enacted several reforms entitled the Medical Device Regulatory Improvements and additional miscellaneous provisions that will further affect medical device regulation both pre -and

post -approval.

If, as a result of legislative or regulatory healthcare reform, we cannot sell the *iStent* (or our other products in development, if approved) profitably, 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.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or PPACA, was signed into law. While the goal of health care reform is to expand coverage to more individuals, it also involves increased government price controls, additional regulatory mandates and other measures designed to constrain medical costs. The PPACA substantially changes the way healthcare is financed by both governmental and private insurers, encourages improvements in the quality of healthcare items and services and significantly impacts the medical device industry. Among other things, the PPACA:

- imposes an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions (described in more detail below), which, under the Protecting Americans from Tax Hikes Act of 2015, or the PATH Act, is suspended from January 1, 2016, to December 31, 2017, and, absent further legislative action, will be reinstated starting January 1, 2018;
- establishes a new Patient -Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research;
- implements payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and
- creates an independent payment advisory board that will submit recommendations to Congress to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislation, will remain in effect through 2025 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. On April 16, 2015, President Obama signed into law the Medicare Access and CHIP Reauthorization Act of 2015, which, among other things, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments scheduled to begin in 2019 that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or product candidates or additional pricing pressures.

In September 2012, the European Commission published proposals for the revision of the EU regulatory framework for medical devices. The proposal would replace the Medical Devices Directive and two related directives concerning active implantable medical devices and in vitro diagnostic medical devices respectively with a new regulation concerning medical devices and another concerning in vitro diagnostic medical devices. Unlike Directives that must be implemented into national laws, the Regulations would be directly applicable in all EEA Member States and so are intended to eliminate current national differences in regulation of medical devices.

In October 2013, the European Parliament approved a package of reforms to the European Commission's proposals. Under the revised proposals, only designated "special notified bodies" would be entitled to conduct

conformity assessments of high -risk devices. These special notified bodies will need to notify the European Commission when they receive an application for a conformity assessment for a new high -risk device. The Commission will then forward the notification and the accompanying documents on the device to the Medical Devices Coordination Group for an opinion. These new procedures may result in the re -assessment of our existing medical devices, or a longer or more burdensome assessment of our new products. We anticipate that further amendments to this proposal may be agreed upon as a compromise among the various EU legislative bodies before the final regulation on medical devices is adopted, most likely in 2016.

The clinical trial process required to obtain regulatory approvals is lengthy and expensive with uncertain outcomes, and could result in delays in new product introductions.

Because of the indication we chose to pursue for the *iStent* , the FDA required that we seek PMA approval rather than clearance under the 510(k) process. In order to obtain PMA approval for a product, the sponsor must conduct well -controlled clinical trials designed to assess the safety and efficacy of the product candidate. Similarly, a sponsor generally must conduct well -controlled clinical trials designed to assess the safety and efficacy of a drug product candidate in order to obtain FDA approval of a drug product. We therefore will be required to conduct clinical trials to obtain approval of *iDose* , our drug delivery implant, new indications for the *iStent* or new product candidates. Conducting clinical trials is a complex and expensive process, can take many years, and outcomes are inherently uncertain. We incur substantial expense for, and devote significant time to, clinical trials but cannot be certain that the trials will ever result in commercial sales. 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. Any of our products may malfunction or may produce undesirable adverse effects that could cause us or regulatory authorities to interrupt, delay or halt clinical trials. We, the FDA, or another regulatory authority may suspend or terminate clinical trials at any time to avoid exposing trial participants to unacceptable health risks.

Successful results of pre -clinical studies are not necessarily indicative of future clinical trial results, and predecessor clinical trial results may not be replicated in subsequent clinical trials. Additionally, the FDA may disagree with our interpretation of the data from our pre -clinical studies and clinical trials, or may find the clinical trial design, conduct or results inadequate to prove safety or efficacy, and may require us to pursue additional pre -clinical studies or clinical trials, which could further delay the clearance or approval of our products. The data we collect from our pre - clinical studies and clinical trials may not be sufficient to support FDA clearance or approval, and if we are unable to demonstrate the safety and efficacy of our future products in our clinical trials, we will be unable to obtain regulatory clearance or approval to market our products.

In addition, we may estimate and publicly announce the anticipated timing of the accomplishment of various clinical, regulatory and other product development goals, which are often referred to as milestones. These milestones could include the obtainment of the right to affix the CE Mark in the European Union; the submission to the FDA of an IDE application, or an IND application, to commence a clinical trial for a new product candidate; the enrollment of patients in clinical trials; the release of data from clinical trials; and other clinical and regulatory events. The actual timing of these milestones could vary dramatically compared to our estimates, in some cases for reasons beyond our control. We cannot assure you that we will meet our projected milestones and if we do not meet these milestones as publicly announced, the commercialization of our products may be delayed and, as a result, our stock price may decline.

Clinical trials are necessary to support PMA applications for our device product candidates and may be necessary to support PMA supplements for modified versions of our marketed device products. This would require the enrollment of large numbers of suitable subjects, which may be difficult to identify, recruit and maintain as participants in the clinical trial. The clinical trials supporting the PMA application for the *iStent* involved 289 randomized patients. We expect that we will provide the FDA with data on the results of approximately 968 patients in three post -approval studies. If the FDA were to require us to submit data on a greater number of patients or a longer follow -up period, we would incur additional expenses that could be significant. Adverse outcomes in the post -approval studies could also result in restrictions or withdrawal of approval of the PMA.

Before we can obtain regulatory approval for any drug product candidate, such as our iDose drug delivery implant, we must undertake extensive clinical testing in humans to demonstrate safety and efficacy to the satisfaction of the FDA and other regulatory agencies. Clinical trials of drug product candidates are expensive and take years to complete, and the outcome of such trials is uncertain. We are currently conducting a Phase I clinical trial of iDose in

Armenia and we expect to commence a Phase II clinical trial of iDose in the United States in early 2016. Our ability to conduct additional clinical trials depends on many factors, including the data obtained in the Phase I and the anticipated Phase II clinical trial.

Delays in the commencement or completion of clinical trials or testing 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. The commencement and completion of clinical trials can be delayed or terminated for a number of reasons, including delays or failures related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical studies;
- obtaining regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- manufacturing sufficient quantities of a product candidate for use in clinical trials;
- obtaining IRB or ethics committees approval to conduct a clinical trial at each prospective site;
- recruiting and enrolling patients and maintaining their participation in clinical trials;
- having clinical sites observe trial protocol or continue to participate in a trial;
- addressing any patient safety concerns that arise during the course of a clinical trial;
- addressing any conflicts with new or existing laws or regulations; and
- adding a sufficient number of clinical trial sites.

Patient enrollment in clinical trials and completion of patient follow ‑up depend on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, patient compliance, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new treatments that may be approved for the indications we are investigating. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post ‑treatment procedures or follow ‑up to assess the safety and efficacy of a product candidate, or they may be persuaded to participate in contemporaneous clinical trials of a competitor's product candidate. In addition, patients participating in our clinical trials may drop out before completion of the trial or suffer adverse medical events unrelated to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may delay commencement or completion of the clinical trial, cause an increase in the costs of the clinical trial and delays, or result in the failure of the clinical trial.

We could also encounter delays if the FDA concluded that our financial relationships with our principal investigators resulted in a perceived or actual conflict of interest that may have affected the interpretation of a study, the integrity of the data generated at the applicable clinical trial site or the utility of the clinical trial itself. Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash compensation and/or stock options in connection with such services. If these relationships and any related compensation to or ownership interest by the clinical investigator carrying out the study result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of our application by the FDA. Any such delay or rejection could prevent us from commercializing any of our products currently in development.

Further, clinical trials may also be delayed as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by us, the FDA, the IRB overseeing the clinical trial at issue, the Data

Safety Monitoring Board for such trial, any of our clinical trial sites with respect to that site, or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with applicable regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- inability of a clinical investigator or clinical trial site to continue to participate in the clinical trial;
- unforeseen safety issues or adverse side effects;
- failure to demonstrate a benefit from using the product candidate; and
- lack of adequate funding to continue the clinical trial.

Additionally, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. If we experience delays in completion of, or if we terminate, any of our clinical trials, the commercial prospects for our product candidates may be harmed and our ability to generate product revenues from these product candidates will be delayed or not realized at all. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of a clinical trial may also ultimately lead to the denial of regulatory approval of the subject product candidate.

If the FDA does not conclude that the iDose drug delivery implant satisfies the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval of the iDose drug delivery implant under Section 505(b)(2) are not as we expect, the approval pathway will likely take significantly longer, cost significantly more and encounter significantly more complications and risks than anticipated, and in any case may not be successful.

We intend to seek FDA approval through the 505(b)(2) regulatory pathway for our drug delivery implant, *iDose* . The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch -Waxman Act, added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant.

If the FDA does not allow us to pursue the 505(b)(2) regulatory pathway for *iDose* as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval would likely substantially increase. Moreover, the inability to pursue the 505(b)(2) regulatory pathway could result in new competitive products reaching the market faster than our product candidate, which could materially adversely impact our competitive position and prospects. In addition, circumstances could change that would render a 505(b)(2) application for the product no longer appropriate. Even if we are allowed to pursue the 505(b)(2) regulatory pathway for *iDose* , we cannot assure you that we will receive the requisite or timely approvals for commercialization of this product candidate.

Failure to comply with post -marketing regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw a product from the market.

Once a medical device is approved, a manufacturer must notify the FDA of any modifications to the device. Any modification to a device that has received FDA clearance or approval that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires premarket clearance or approval from the FDA pursuant to a new 510(k) clearance or approval of a PMA supplement. The FDA requires every manufacturer to make the determination in the first instance regarding whether a modification to a cleared or approved device necessitates the filing of a new 510(k) notification or PMA supplement. The FDA may review any manufacturer’s decision and can disagree. If the FDA disagrees with any future determination by us that a new clearance

or approval is not required, we may need to cease marketing or to recall the modified product until and unless we obtain clearance or approval. In addition, we could also be subject to significant regulatory fines or penalties. Any of these outcomes could harm our business.

A manufacturer must also submit periodic reports to the FDA as a condition of PMA approval. These reports include safety and effectiveness information about the device after its approval. Failure to submit such reports, or failure to submit the reports in a timely manner, could result in enforcement action by the FDA. Following its review of the periodic reports, the FDA might ask for additional information or initiate further investigation.

The PMA approval for the *iStent* is subject to several conditions of approval, including postmarket study and registry study requirements. Failure to comply with the conditions of approval could result in the withdrawal of PMA approval, and the inability to continue to market the device. Failure to conduct the required studies in accordance with IRB and informed consent requirements could also be grounds for withdrawal of approval of the PMA.

The regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. 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. The FDA, state and foreign regulatory authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory authorities, which may include any of the following sanctions:

- untitled letters or warning letters;
- fines, injunctions, consent decrees and civil penalties;
- recalls, termination of distribution, administrative detention, or seizure of our products;
- customer notifications or repair, replacement or refunds;
- operating restrictions or partial suspension or total shutdown of production;
- delays in or refusal to grant our requests for future 510(k) clearances, PMA approvals or foreign regulatory approvals of new products, new intended uses, or modifications to existing products;
- withdrawals or suspensions of current 510(k) clearances or PMAs or foreign regulatory approvals, resulting in prohibitions on sales of our products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and
- criminal prosecution.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, results of operations and financial condition.

We must continually monitor the performance of our products once approved and marketed for signs that their use may elicit serious and unexpected adverse effects. Any recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products that leads to corrective actions, could have a significant adverse impact on us.

Our ability to achieve our strategic objectives will depend, among other things, on the long-term clinical performance of the *iStent* for lowering intraocular pressure in mild-to-moderate open-angle glaucoma patients undergoing cataract surgery. Our original PMA approval for the *iStent* included several post-marketing study requirements and future approvals may be subject to similar requirements. Failure to conduct required post-marketing studies in a timely manner could result in the revocation of the clearance or approval for the product that is subject to such a requirement and could also result in the recall or withdrawal of the product, which would prevent us from generating sales from that product in the United States.

Although we believe follow ‑up at two years continues to support efficacy and safety of the *iStent* for lowering intraocular pressure in mild ‑to ‑moderate open ‑angle glaucoma patients undergoing cataract surgery, in the future, longer term study outcomes could demonstrate conflicting clinical effectiveness, a reduction of effectiveness, no clinical effectiveness or longer term safety issues with the *iStent* . This type of differing data could have a detrimental effect on the market penetration and usage of the *iStent* by customers treating mild ‑to ‑moderate open ‑angle glaucoma and/or the risk/benefit profile of using the *iStent* to treat mild ‑to ‑moderate open ‑angle glaucoma in combination with cataract surgery. As a result, our sales may decline or expected growth would be negatively impacted. This could put pressure on our ability to execute key components of our business strategy and/or negatively impact our operating condition and financial results.

More generally, all medical devices, such as the *iStent* , can experience performance problems that require review and possible corrective action by us or a component supplier. We cannot provide assurance that component failures, manufacturing errors, noncompliance with quality system requirements or good manufacturing practices, design defects and/or labeling inadequacies in any device or drug products that could result in an unsafe condition or injury to the patient will not occur. The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. Manufacturers may also, under their own initiative, stop shipment or recall a product if any material deficiency is found or withdraw a product to improve device performance or for other reasons. A government ‑mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, noncompliance with good manufacturing practices or quality system requirements, design or labeling defects or other deficiencies and issues. Similar regulatory agencies in other countries have similar authority to recall products because of material deficiencies or defects in design or manufacture that could endanger health. Any recall would divert management attention and financial resources, could cause the price of our stock to decline and expose us to product liability or other claims and harm our reputation with customers. A recall involving our products could be particularly harmful to our business, financial and operating results.

The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. Notice to the FDA of a correction or removal is required when undertaken to reduce a risk to health, including when there is a reasonable probability that the product will cause serious adverse health consequences or death, or when use of the device may cause temporary or medically reversible adverse health consequences or an outcome where the probability of serious adverse health consequences is remote. In addition, companies are required to maintain certain records of corrections and removal, even if they are not reportable to the FDA or similar foreign governmental authorities. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA or foreign governmental authorities. If the FDA or foreign governmental authorities disagree with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA or a foreign governmental authority could take enforcement action for failing to report the recalls when they were conducted.

In addition, under the FDA's medical device reporting regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall. We are subject to similar obligations in the EEA and other countries in which we market our products.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA or applicable foreign regulatory authority may require, or we may decide, that we will need to obtain new approvals or clearances for the device before we may market or distribute the corrected device. Seeking such approvals or clearances may delay our ability to replace the recalled devices in a timely manner. Moreover, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties, civil penalties or criminal fines. We may also be required to bear other costs or take other actions that may have a negative impact on our sales as well as face significant adverse publicity or regulatory consequences, which could harm our business, including our ability to market our products in the future.

Any adverse event involving our products, whether in the United States or abroad, could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection, mandatory recall, orders of repair, replacement or refund or other enforcement action. Any corrective action, whether voluntary or

involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

If we or our component manufacturers fail to comply with the FDA's Quality System Regulation or Good Manufacturing Practice regulations, our manufacturing operations could be interrupted, and our product sales and operating results could suffer.

We and some of our component manufacturers are required to comply with regulatory requirements known as the FDA's QSR, which covers the procedures and documentation of the design, testing, production, control, quality assurance, inspection, complaint handling, recordkeeping, management review, labeling, packaging, sterilization, storage and shipping of our device products. The FDA's cGMPs apply to the manufacture of drug substance and finished drug products. The FDA audits compliance with these regulatory requirements through periodic announced and unannounced inspections of manufacturing and other facilities. The FDA may conduct inspections or audits at any time, and we and some of our component suppliers are subject to such inspections. Although we believe our manufacturing facilities and those of our critical component suppliers are in compliance with the QSR requirements, and with applicable cGMPs for our *iDose* drug delivery implant, we cannot provide assurance that any future inspection will not result in adverse findings. If our manufacturing facilities or those of any of our component suppliers are found to be in violation of applicable laws and regulations, or we or our suppliers have significant noncompliance issues or fail to timely and adequately respond to any adverse inspectional observations or product safety issues, or if any corrective action plan that we or our suppliers propose in response to observed deficiencies is not sufficient, the FDA could take enforcement action, including any of the following sanctions:

- untitled letters or warning letters;
- fines, injunctions, consent decrees and civil penalties;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for clearance or approval of new products or modified products;
- withdrawing clearances or approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Any of these sanctions could adversely affect our business, financial conditions and operating results.

Outside the United States, our products and operations are also often required to comply with standards set by industrial standards bodies, such as the ISO. Foreign regulatory bodies may evaluate our products or the testing that our products undergo against these standards. The specific standards, types of evaluation and scope of review differ among foreign regulatory bodies. If we fail to adequately comply with any of these standards, a foreign regulatory body may take adverse actions similar to those within the power of the FDA. Any such action may harm our reputation and could have an adverse effect on our business, results of operations and financial condition.

If we fail to obtain and maintain regulatory approval in foreign jurisdictions, our market penetration opportunities will be limited.

The *iStent* is currently approved for sale in 27 c ountries outside of the United States, where it is sold through a direct sales network in Germany as well as distributors in other countries. In order to market our products in the European Union, Asia or other foreign jurisdictions, we must obtain and maintain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies from country to country and can involve additional testing. The time required to obtain approval abroad may be longer than the time required to obtain FDA clearance or approval. Foreign regulatory approval processes include many of the risks associated with obtaining FDA clearance or approval and we may not obtain foreign regulatory approvals on a timely basis, if at all. FDA clearance or approval does not ensure approval by regulatory authorities in other countries, and approval by one

foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries. However, the failure to obtain clearance or approval in one jurisdiction may have a negative impact on our ability to obtain clearance or approval elsewhere. If we do not obtain or maintain necessary approvals to commercialize our products in markets outside the United States, it would negatively affect our overall market penetration.

We may be subject to fines, penalties, injunctions or other enforcement actions if we are determined to be promoting the use of our products for unapproved or "off-label" uses, resulting in damage to our reputation and business.

Our promotional materials 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. Use of a drug or device outside of its cleared or approved indications is known as "off-label" use. Physicians may use our products off-label, 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 or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of warning letters, untitled letters, fines, penalties, consent decrees, injunctions, or seizures, which could have an adverse impact on our reputation and financial results. We could also be subject to enforcement action under other federal or state laws, including the federal FCA.

Failure to comply with the Federal Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act, and implementing regulations affecting the transmission, security and privacy of health information could result in significant penalties.

Numerous federal and state laws and regulations, including the Federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, and the Health Information Technology for Economic and Clinical Health Act, or HITECH Act, govern the collection, dissemination, security, use and confidentiality of patient-identifiable health information. HIPAA and the HITECH Act may require us to comply with standards for the use and disclosure of health information within our company and with third parties. The Privacy Standards and Security Standards under HIPAA establish a set of basic national privacy and security standards for the protection of individually identifiable health information by health plans, healthcare clearinghouses and certain healthcare providers, referred to as covered entities, and the business associates with whom such covered entities contract for services. Notably, whereas HIPAA previously directly regulated only these covered entities, the HITECH Act, which was signed into law as part of the stimulus package in February 2009, makes certain of HIPAA's privacy and security standards also directly applicable to covered entities' business associates. As a result, both covered entities and business associates are now subject to significant civil and criminal penalties for failure to comply with the Privacy Standards and Security Standards.

HIPAA and the HITECH Act also include standards for common healthcare electronic transactions and code sets, such as claims information, plan eligibility and payment information. Covered entities, such as healthcare providers, are required to conform to such transaction set standards pursuant to HIPAA.

HIPAA requires healthcare providers to develop and maintain policies and procedures with respect to protected health information that is used or disclosed, including the adoption of administrative, physical and technical safeguards to protect such information. The HITECH Act expands the notification requirement for breaches of patient-identifiable health information, restricts certain disclosures and sales of patient-identifiable health information and provides a tiered system for civil monetary penalties for HIPAA violations. The HITECH Act also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney fees and costs associated with pursuing federal civil actions. Additionally, certain states have adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA.

If we do not comply with applicable existing or new laws and regulations related to patient health information, we could be subject to criminal or civil sanctions. New health information standards, whether implemented pursuant to HIPAA, the HITECH Act, congressional action or otherwise, could have a significant effect on the manner in which we handle healthcare-related data and the cost of complying with these standards could be significant.

The 2013 final HITECH Act omnibus rule modified the breach reporting standard in a manner that will likely make more data security incidents qualify as reportable breaches. Any liability from a failure to comply with the applicable requirements of HIPAA or the HITECH Act could adversely affect our financial condition. The costs of

complying with privacy and security ‑related legal and regulatory requirements are burdensome and could have a material adverse effect on our results of operations. These provisions, as modified, will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us, as well as our clients and strategic partners. In addition, we are unable to predict what changes to the HIPAA Privacy Standards and Security Standards might be made in the future or how those changes could affect our business. Any new legislation or regulation in the area of privacy and security of personal information, including personal health information, could also adversely affect our business operations.

If we fail to comply with state and federal healthcare regulatory laws, we could face substantial penalties, damages, fines, disgorgement, exclusion from participation in governmental healthcare programs, and the curtailment of our operations, any of which could adversely affect our business, operations, and financial condition.

Although we do not provide healthcare services, submit claims for third ‑party reimbursement, or receive payments directly from Medicare, Medicaid or other third ‑party payors for our products, we are subject to healthcare fraud and abuse regulation and enforcement by federal and state governments, which could significantly impact our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti ‑Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it;
- the civil FCA, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third ‑party payors that are false or fraudulent; knowingly making using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government; or knowingly making, using, or causing to be made or used, a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the criminal FCA, which imposes criminal fines or imprisonment against individuals or entities who make or present a claim to the government knowing such claim to be false, fictitious or fraudulent;
- HIPAA, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the federal civil monetary penalties statute, which prohibits, among other things, the offering or giving of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary’s selection of a particular supplier of items or services reimbursable by a Federal or state governmental program;
- the federal physician sunshine requirements under PPACA, which require certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to the U.S. Department of Health and Human Services information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members. The period between August 1, 2013 and December 31, 2013 was the first reporting period, and manufacturers were required to report aggregate payment data by March 31, 2014, and to report detailed payment data and submit legal attestation to the accuracy of such data by June 30, 2014. Thereafter, manufacturers must submit reports by the 90th day of each subsequent calendar year; and
- state law equivalents of each of the above federal laws, such as anti ‑kickback and false claims laws that may apply to items or services reimbursed by any third ‑party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the device industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state

laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

Further, the PPACA, among other things, amended the intent requirements of the federal Anti-Kickback Statute and certain criminal statutes governing healthcare fraud. A person or entity can now be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, PPACA provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. Moreover, while we do not submit claims and our customers make the ultimate decision on how to submit claims, from time to time, we may provide reimbursement guidance to our customers. If a government authority were to conclude that we provided improper advice to our customers or encouraged the submission of false claims for reimbursement, we could face action against us by government authorities. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

We have entered into consulting and scientific advisory board arrangements with physicians and other healthcare providers, including some who influence the ordering of and use of our products in procedures they perform. Compensation for some of these arrangements includes the provision of stock options. In addition, in connection with our clinical trial recruitment activities, we have entered into compensation arrangements with some of the physicians who recruit subjects to our clinical trials. While we believe we are in material compliance with applicable laws, because of the complex and far-reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or that affect our ability to use all of the data from the clinical trial to support our marketing applications, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with providers who influence the ordering of and use our products to be in violation of applicable laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time- and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including 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.

Foreign governments tend to impose strict price controls, which may adversely affect our future profitability.

We currently sell the *iStent* and *iStent Inject* outside the United States and we plan to further expand our international operations. In some foreign countries, particularly in the European Union, the pricing of medical devices is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to supply data that compares the cost-effectiveness of our products to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, it may not be profitable to sell our products in certain foreign countries, which could negatively affect the long-term growth of our business.

Our financial performance may be affected by medical device tax provisions in the healthcare reform laws.

The PPACA imposes among other things, an excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States beginning in 2013. Under these provisions, the Congressional Research Services predicted that the total cost to the medical device industry may be up to $29 billion over the next

decade. The *iStent* has been subject to this tax and the other products in our pipeline potentially will be subject to this tax.

On December 18, 2015, the President signed into law the PATH Act, which includes a two -year moratorium on the medical device excise tax. This Act amends the Internal Revenue Code to exempt medical device sales during the period of January 1, 2016 to December 31, 2017. Absent further legislation, the tax will be automatically reinstated for medical device sal es starting on January 1, 2018.

There are no assurances that our business will not be materially adversely affected by the current, or possible future additional tax, provisions implemented under healthcare reform or appropriate legislation.

Our operations involve hazardous materials, and we must comply with environmental laws and regulations, which can be expensive.

We are subject to a variety of federal, state and local regulations relating to the use, handling, storage, disposal, and human exposure to hazardous and toxic materials. We could incur costs, fines, and civil and criminal sanctions, third -party property damage or personal injury claims, or could be required to incur substantial investigation or remediation costs, if we were to violate or become liable under environmental laws. Compliance with current or future environmental and safety laws and regulations could restrict our ability to expand our facilities, impair our research, development or production efforts, or require us to incur other significant expenses. There can be no assurance that violations of environmental laws or regulations will not occur in the future as a result of the inability to obtain permits, human error, accident, equipment failure or other causes.

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 maintain and protect our proprietary 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 intellectual property. These legal means, however, afford only limited protection and may not adequately protect our intellectual property rights. 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 that, if issued, they will issue in a form that will be advantageous to us. The United States Patent and Trademark Office, or USPTO, or other foreign patent offices may deny or significantly narrow claims made under our patent applications and our issued patents may be successfully challenged, may be designed around, or may otherwise be of insufficient scope to provide us with any meaningful protection for our present or future commercial products. Further, the USPTO or other foreign trademark offices may deny our trademark applications and, even if published or registered, these trademarks may be ineffective in protecting our brand and goodwill and may be successfully opposed or challenged.

The patent prosecution process itself is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. The patent prosecution process requires compliance with complex laws, rules and regulations imposed by patent authorities. Failure to comply with these laws, rules and regulations may derive, among other bases, from various defects of form in the preparation or filing of our patents or patent applications, which may include defects that relate to our making proper priority claims and inventorship determinations. If any such defects are identified, we may need to take corrective action. For example, we have filed petitions with the USPTO to request in part that Dr. Richard Hill, one of our consultants, be added as an inventor on patents related to our *iStent* and *iStent Inject* products and *iStent Supra* product candidate that were developed during Dr. Hill's consultancy. Dr. Hill has assigned his rights in these patents and certain other patent applications to us pursuant to the terms of his consulting agreement . We cannot assure you, however, that our petitions to the USPTO will be successful. Dr. Hill was employed as an Associate Professor at the University of California, Irvine, or the University, during the period when these patents and patent applications were developed. We engaged in discussions with the University to address whether it has any ownership claim to these patents and patent applications as a result of Dr. Hill's employment, and in December 2014, we entered into an agreement with the University pursuant to which the

University agreed not to challenge our ownership of these patents and patent applications. In addition, if any material defects are found in the form or preparation of any of our patents or patent applications, such patents or applications may be invalid and unenforceable. Any of these outcomes could impair our ability to prevent competition from third parties, which could harm our business. Moreover, the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. N oncompliance with these requirements can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we fail to maintain the patents and patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our products, which would have a material adverse effect on our business.

The patent position of medical device companies is generally highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In the United States and in many foreign jurisdictions, policies regarding the breadth of claims allowed in patents can be inconsistent. The U.S. Supreme Court and the Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, foreign courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially affect our patents or patent applications and our ability to obtain patents. Future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage, which could adversely affect our business, financial condition and results of operations.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy -Smith America Invents Act, or the Leahy -Smith Act, was signed into law. The Leahy -Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation, and switch the U.S. patent system from a “first -to -invent” system to a “first -to -file” system. Under a “first -to -file” system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO developed new regulations and procedures to govern administration of the Leahy -Smith Act, and many of the substantive changes to patent law associated with the Leahy -Smith Act, and in particular, the first -to -file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy -Smith Act will have on the operation of our business. However, the Leahy -Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement, and defense of our patents and applications.

We may be subject to a third -party preissuance submission of prior art to the USPTO or to another foreign patent office, or become involved in opposition, derivation, reexamination, inter partes review, post -grant review, or other patent office proceedings or litigation, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third -party patent rights.

We have a number of 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 product offerings 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 such 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 we are otherwise precluded from effectively protecting our intellectual property rights in these jurisdictions, our business, financial condition and results of operations could be substantially harmed.

Despite our efforts to safeguard our unpatented and unregistered intellectual property rights, we may not be successful in doing so, or the steps taken by us in this regard may not be adequate to detect or deter misappropriation of our technology or to prevent an unauthorized third party from copying or otherwise obtaining and using our products, technology or other information that we regard as proprietary. 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. Our inability to adequately protect our intellectual property could allow our competitors and other third parties to produce products based on our patented or proprietary technology and other intellectual property rights, which could substantially impair our ability to compete.

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.

We have been and may in the future become involved in patent and other intellectual property litigation or administrative proceedings to enforce or defend our intellectual property rights, which could be costly, time consuming and unsuccessful and could interfere with our ability to successfully commercialize our products .

We have asserted and may in the future need to assert claims of infringement against third parties to protect our intellectual property.

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. Any claims we assert against alleged infringers could provoke these third parties to assert counterclaims against us alleging that we infringe their own intellectual property rights, or that our rights are invalid or unenforceable. 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. Any such adverse result would undermine our competitive position. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could hurt the price of our common stock. Such litigation proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

We may become subject to claims of infringement or misappropriation of the intellectual property rights of others, which could prohibit us from selling our products, require us to obtain licenses from third parties, require us to develop non-infringing alternatives and/or subject us to substantial monetary damages and injunctive relief.

The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. Moreover, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that materially and adversely affect our business. Additionally, our competitors could later pursue additional patent protection related to their earlier patent disclosures, where such patent filings are prepared with intent to cover our products. Third parties could also assert infringement or misappropriation claims against us with respect to our products. Whether or not such claims are valid, we cannot be certain that we have not infringed the intellectual property rights of such third parties or others. Additionally, for business reasons, we may seek to invalidate or challenge the intellectual property rights of a third party, including those rights owned by our competitors, before any infringement assertion is made. This action could include seeking a declaration from a court that one or more of our products do not infringe one or more patents or other intellectual property rights owned by third parties.

Any infringement or misappropriation claim or validity or infringement challenge could result in significant costs, substantial damages and our inability to manufacture, market or sell our existing or future products that are found to infringe. Even if we were to prevail in any such action, the litigation could result in substantial cost and diversion of

resources that could materially and adversely affect our business. If a court determined, or if we independently discovered, that our product offerings violated third-party proprietary rights, there can be no assurance that we would be able to re-engineer our products to avoid those rights or to obtain a license under those rights on commercially reasonable terms, if at all. As a result, we could be prohibited from selling products that are found to infringe, or we could elect not to sell or to stop selling products that we believe have a substantial probability of infringing a third-party's intellectual property rights. Even if obtaining a license were feasible, it may be costly and time-consuming. A court could also enter orders that temporarily, preliminarily or permanently enjoin us or our customers from making, using, selling, offering to sell, distributing, exporting or importing the *iStent* or future products, such as the *iStent Inject* , *iStent Supra* or *iDose* , or could enter orders mandating that we undertake certain remedial activities. A court could also order us to pay compensatory damages for such infringement, plus prejudgment interest, and if we are found to have willfully infringed third-party rights, could in addition treble the compensatory damages and award attorneys' fees. These damages could be substantial and could harm our reputation, business, financial condition and results of operations.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could hurt the price of our common stock. Such litigation proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

If any of our employees, consultants or others breach their proprietary information agreements, our competitive position could be harmed.

We protect our proprietary technology, in part, through proprietary information and inventions agreements with employees, consultants and other parties. These agreements with employees and consultants generally contain standard provisions requiring those individuals to assign to us, without additional consideration, inventions conceived or reduced to practice by them while employed or retained by us, subject to customary exceptions. 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 such 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. As a result, our competitors may learn our trade secrets or we may be required to pursue litigation in order to determine the ownership of the intellectual property rights at issue.

Even if we file suit to prevent or stop such disclosure, there is a risk that a court could find we have not adequately protected the information as a trade secret and allow use of the disclosed information by our competitors. Additionally, we may need to file suit to force the employee, consultant or other party in breach to assign his, her or its rights to us, or we may need to pay additional compensation to such employee, consultant or other party in order to quiet or obtain legal title to the intellectual property rights at issue.

We may be subject to claims that we or our employees have misappropriated the intellectual property of a third party, including trade secrets or know-how, or are in breach of non-competition or non-solicitation agreements with our competitors and third parties may claim an ownership interest in intellectual property we regard as our own.

Many of our employees and consultants were previously employed at or engaged by other medical device, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants and contractors, may have executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, 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 former employers or competitors. Additionally, we may be subject to claims from third parties challenging our ownership interest in

intellectual property we regard as our own, based on claims that our employees or consultants have breached an obligation to assign inventions to another employer, to a former employer, or to another person or entity. For example, Dr. Hill, one of our consultants, was also employed as an Associate Professor at the University during the period when certain patents and patent applications to which Dr. Hill contributed were developed. We have discussed with the University whether it has any ownership claim to these patents as a result of Dr. Hill's employment. In December 2014, we entered into an agreement with the University pursuant to which the University agreed not to challenge our ownership of the patents and patent applications to which Dr. Hill contributed while he was both a consultant for us and a faculty member at the University. Litigation may be necessary to defend against any other claims, and it may be necessary or we may desire to enter into a license to settle any such claim; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate technologies or features that are important or essential to our products could have a material adverse effect on our business, and may prevent us from selling our products. In addition, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could have an adverse effect on our business, results of operations and financial condition.

Risks Related to Being a Public Company

We are incurring increased costs as a result of operating as a public company and our management is required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we are incurring, and increasingly after we are no longer an "emerging growth company," we will incur, significant legal, accounting, administrative and other costs and expenses that we did not previously incur as a private company. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes -Oxley Act of 2002 (Sarbanes -Oxley Act) and rules subsequently implemented by the SEC and the New York Stock Exchange (NYSE) impose numerous requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Further, pursuant to the Dodd -Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory "say on pay" voting requirements that will apply to us when we cease to be an emerging growth company. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and may impact the manner in which we operate our business in ways we cannot currently anticipate. Our management and other personnel need to devote a substantial amount of time to compliance with these laws and regulations. These requirements have increased and will continue to increase our legal, accounting and financial compliance costs and have made and will continue to make some activities more time consuming and costly. These rules and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or our board committees or as executive officers.

The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

If we experience material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

The Sarbanes ‑Oxley Act requires, among other things, that we assess the effectiveness of our internal control over financial reporting annually and the effectiveness of our disclosure controls and procedures quarterly. In particular, Section 404(a) of the Sarbanes ‑Oxley Act will require us to perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting. Section 404(b) of the Sarbanes ‑Oxley Act also requires our independent registered public accounting firm to attest to the effectiveness of our internal control over financial reporting. As an "emerging growth company" we expect to avail ourselves of the exemption from the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404(b). However, we may no longer avail ourselves of this exemption when we are no longer an "emerging growth company." When our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, the cost of our compliance with Section 404(b) will correspondingly increase. Our compliance with applicable provisions of Section 404 will require that we incur substantial accounting expense and expend significant management time on compliance ‑related issues as we implement additional corporate governance practices and comply with reporting requirements.

Furthermore, investor perceptions of our company may suffer if deficiencies are found, and this could cause a decline in the market price of our stock. Regardless of compliance with Section 404, any failure of our internal control over financial reporting could have a material adverse effect on our stated operating results and harm our reputation. If we are unable to implement these requirements effectively or efficiently, it could harm our operations, financial reporting, or financial results and could result in an adverse opinion on our internal controls from our independent registered public accounting firm.

We are an "emerging growth company," and the reduced disclosure requirements applicable to such companies could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act (JOBS Act), enacted in April 2012, and may remain an "emerging growth company" until the last day of the fiscal year following the fifth anniversary of the completion of our IPO. However, if certain events occur prior to the end of such five ‑year period, including if we become a "large accelerated filer," our annual gross revenues equals or exceeds $1.0 billion or we issue more than $1.0 billion of non ‑convertible debt in any three ‑year period, we will cease to be an emerging growth company prior to the end of such five ‑year period. For as long as we remain an "emerging growth company," we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not "emerging growth companies." These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's discussion and analysis of financial condition and results of operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

If some investors find our common stock less attractive as a result of our decision to rely on these exemptions, there may be a less active trading market for our common stock and our stock price may be reduced or become more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We have elected not to avail ourselves of this exception and therefore will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Risks Related to our Common Stock and Ownership of Our Common Stock

Our common stock has only been publicly -trading since June 25, 2015, and we expect that the price of our common stock will fluctuate substantially.

Before our IPO, there was no public market for our common stock. Although our common stock began trading on the NYSE in June 2015, an active public trading market may not be sustained. The market price for our common stock will be affected by a number of factors, including:

- the depth and liquidity of the market for our common stock;
- volume, timing and nature of orders for our products;
- developments generally affecting medical device companies;
- actual or anticipated quarterly variation in our results of operations or the results of our competitors;
- the announcements by us or our competitors of new products or product enhancements, significant contracts, commercial relationships or capital commitments;
- developments or disputes concerning our intellectual property or other proprietary rights;
- issuance of new or changes in earnings estimates or recommendations or reports by securities analysts;
- investor perceptions of us and our business, including changes in market valuations of medical device companies;
- actions by institutional or other large stockholders;
- commencement of, or our involvement in, litigation;
- failure to complete significant sales;
- manufacturing disruptions that could occur if we were unable to successfully expand our production in our current or an alternative facility;
- any future sales of our common stock or other securities;
- any major change to the composition of our board of directors or management;
- our results of operations and financial performance; and
- general economic, industry and market conditions.

In addition, the NYSE has experienced significant volatility with respect to medical device, medical technology, pharmaceutical, biotechnology and other life science company stocks. The volatility of medical device, medical technology, pharmaceutical, biotechnology and other life science company stocks often does not relate to the operating performance of the companies represented by the stock. Further, there has been particular volatility in the market price of securities of early -stage and development -stage life science and medical device companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance.

If securities or industry analysts publish unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will rely in part on the research and reports that equity research analysts publish about us and our business. We will not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our

company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

We could be subject to securities class action litigation.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted. A securities class action suit against us could result in substantial costs, potential liabilities and the diversion of management's attention and resources.

Our officers, directors and principal stockholders have significant voting power and may take actions that may not be in the best interests of our other stockholders.

Our executive officers, directors and stockholders holding more than 5% of our outstanding common stock currently collectively own or control a majority of our outstanding common stock. As a result, our executive officers, directors and stockholders holding more than 5% of our outstanding common stock, acting as a group, have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transactions. These stockholders may also have the effect of delaying or preventing a change in control of us, even if such a change of control would benefit our other stockholders. This significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

Two members of our board of directors are directors of DOSE. In addition, there is significant overlap between our current stockholders and the stockholders of DOSE. Their interests may conflict with those of our other stockholders.

Two of our current directors, Thomas W. Burns and William J. Link, Ph.D., serve as the only two members of the board of directors of DOSE. This could result in conflicts of interest between their obligations to our company and DOSE. In addition, there is significant overlap between our stockholders and the stockholders of DOSE. DOSE's interests and the interests of its stockholders may be different from ours or those of our other stockholders and this could result in conflicts. The resolution of any of these conflicts may not always be in our or your best interest.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management and limit the market price of our common stock.

Provisions in our restated certificate of incorporation and amended and restated bylaws may have the effect of delaying or preventing a change of control or changes in our management. Our restated certificate of incorporation and amended and restated 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 effected 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;
- establish that our board of directors is divided into three classes, Class I, Class II and Class III, 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 for stockholders 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.

We have never paid dividends on our capital stock and do not anticipate paying cash dividends in the foreseeable future.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Accordingly, you may have to sell some or all of your shares of our common stock in order to generate cash flow from your investment. You may not receive a gain on your investment when you sell shares and you may lose the entire amount of the investment.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

As of December 31, 2015, we leased or owned app roximately 61,615 square feet of office and operations space in the U.S . This space includes our corporate headquarters and production facilities in Laguna Hills, California and our future headquarters in San Clemente, California. We also have smaller administrative offices and sales offices in in the United States, Germany, Australia , Canada and Japan .

ITEM 3. LEGAL PROCEEDINGS

On October 29, 2015, we entered into a settlement agreement with Transcend (which has entered into a definitive agreement to be acquired by Alcon, Inc., a division of Novartis International AG, which is a publicly traded multinational pharmaceutical company based in Basel, Switzerland) to resolve the patent litigation described above in Item 1, “Business,” and, on October, 29, 2015, the court dismi ssed the matter with prejudice.

We are not presently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. We may from time to time be involved in various claims and legal proceedings of a nature we believe are normal and incidental to a medical device business. These matters may include product liability, intellectual property, such as the matter described below, employment and other general claims. We accrue for contingent liabilities when it is probable that a liability has been incurred and the amount can be reasonably estimated. Regardless of outcome, litigation can have an adverse impact on us because defense and settlement costs, diversion of management resources and other factors.

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 began trading on the NYSE under the symbol "GKOS" on June 25, 2015. Prior to that date, there was no public market for our common stock. Our initial public offering was priced at $18.00 per share on June 25, 2015. The table sets forth, for the periods indicated below, the high and low intra‑day sales prices per share of our common stock as reported on the NYSE since June 25, 2015.

	High	Low
2015		
Second Quarter	$ 31.95	$ 27.39
Third Quarter	$ 33.92	$ 21.59
Fourth Quarter	$ 27.64	$ 18.53

As of March 7 , 2016, we had 85 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 of an investment of $100 at the close of market on June 25, 2015 (the first day of trading of our common stock on the NYSE) 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 all

dividends were reinvested. Stockholder returns over the indicated period should not be considered indicative of future stockholder returns.

	6/25/2015	12/31/2015
GKOS	$ 100	$ 79.08
S&P Small Cap 600 index	$ 100	$ 92.03
S&P Small Cap 600 Healthcare index	$ 100	$ 98.73

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 of 1933, as amended, 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. In addition, our ability to pay dividends may be restricted by the terms of any future credit agreement or any future debt or preferred equity securities of us or of our subsidiaries Payment of future cash dividends, if any, will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs, the requirements of then existing debt instruments and other factors our board of directors may deem relevant.

ITEM 6. SELECTED FINANCIAL DAT A

The selected consolidated financial information set forth below for each of the years ended December 31, 2015, 2014 and 2013 has been derived from our audited consolidated financial statements. The information below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the audited consolidated financial statements and notes thereto included in Items 7 and 8, respectively, of t his Annual Report on Form 10-K.

	Year ended December 31,		
(amounts in thousands, except per share amounts)	2015	2014	2013
Statements of Operations Data:			
Net sales	$ 71,700	$ 45,587	$ 20,946
Cost of sales	12,988	11,418	2,535
Gross profit	58,712	34,169	18,411
Operating expenses:			
Selling, general and administrative	43,961	28,135	17,098
Research and development	25,047	19,205	15,511
Total operating expenses	69,008	47,340	32,609
Loss from operations	(10,296)	(13,171)	(14,198)
Loss on deconsolidation of DOSE	(25,685)	—	—
Total other expense, net	(2,307)	(868)	(23)
Provision for income taxes	33	18	6
Net loss	$ (38,321)	$ (14,057)	$ (14,227)
Net loss attributable to noncontrolling interest	(1,080)	(1,931)	(1,588)
Net loss attributable to Glaukos Corporation	$ (37,241)	$ (12,126)	$ (12,639)
Net loss per share, basic and diluted, attributable to Glaukos Corporation stockholders	$ (2.13)	$ (5.29)	$ (6.21)
Weighted average shares used to compute basic and diluted net loss per share attributable to Glaukos Corporation stockholders	17,474	2,294	2,036

	As of December 31,		
(amounts in thousands)	2015	2014	2013
Balance Sheet Data:			
Cash and cash equivalents	$ 21,572	$ 2,304	$ 6,728
Short-term investments	69,552	—	—
Net working capital (deficit)	83,778	(9,633)	6,487
Total assets	116,661	26,021	30,877
Total liabilities	21,470	29,546	23,709
Convertible preferred stock	—	157,379	156,210
Additional paid in capital	291,853	8,155	6,073
Total stockholders' equity (deficit)	95,191	(151,299)	(141,298)
Noncontrolling interest	—	(9,605)	(7,744)
Total equity (deficit)	95,191	(160,904)	(149,042)

ITEM 7 . MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL COND ITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with "Selected financial data" and our audited consolidated financial statements and related notes included in Items 6 and 8 , respectively, of 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 company focused on the development and commercialization of breakthrough products and procedures designed to transform the treatment of glaucoma, one of the world's leading causes of blindness. We have pioneered Micro -Invasive Glaucoma Surgery, or MIGS, to revolutionize the traditional glaucoma treatment and management paradigm. We launched the *iStent* , our first MIGS device, in the United States in July 2012 and we are leveraging our platform technology to build a comprehensive and proprietary portfolio of micro -scale injectable therapies designed to address the complete range of glaucoma disease states and progression.

The *iStent* is the first commercially available MIGS treatment solution. FDA -approved for insertion in combination with cataract surgery, the *iStent* has been shown to lower intraocular pressure in adult patients with mild -to -moderate open -angle glaucoma, which represents the majority of glaucoma cases. The *iStent* procedure is currently reimbursed by Medicare and a majority of commercial payors.

We are building a broad portfolio of micro -scale injectable therapies designed to address the complete range of glaucoma disease states and progression, including three innovative pipeline products: the *iStent Inject* , the *iStent Supra* and *iDose* . The *iStent Inject* includes two stents pre -loaded in an auto -injection inserter. We are developing two versions of this product: the first is currently being studied for lowering intraocular pressure in conjunction with cataract surgery in a U.S. investigational device exemption, or IDE, pivotal trial; the second is currently being studied in an initial U.S. IDE study as a standalone treatment for lowering intraocular pressure. This second version is also capable of making its own self -sealing corneal penetration, potentially offering patient treatment in a minor surgical suite or an in -office setting. The *iStent Supra* is designed to access an alternative drainage space within the eye where we estimate 20% of aqueous humor outflow occurs, and is now in a U.S. pivotal IDE trial. *iDose* is an implant that is designed to provide a sustained release of a prostaglandin drug to lower intraocular pressure in glaucoma patients. To validate the safety and efficacy of our *iStent* products, we are currently conducting 17 prospective clinical trials.

We have never been profitable and have incurred operating losses in each year since our inception . Our net sales increased to $71.7 million in 2015 from $45.6 million in 2014 and $20.9 million in 2013, and our net losses were $38.3 million, $14.1 million and $14.2 million for the years ended December 31, 2015, 2014 and 2013, respectively . As of December 31, 2015, we had an accumulated deficit of $ 196.6 million.

We have made and expect to continue to make significant investments in our global sales force and marketing programs.

Costs for FDA -approved IDE studies in our industry are expensive as are the costs to develop new products, and we expect to incur a significant increase in administrative costs as we begin operating as a public company. While the gross profits from our growing net sales will help offset some of these costs, we expect to invest significantly more resources into our business using proceeds from the IPO, that we completed on June 30, 2015. Accordingly, we expect to continue to experience net losses for the foreseeable future.

On June 30, 2015, we completed our IPO, selling 6.9 million newly issued shares of common stock at a price of $18.00 per share, pursuant to a Registration Statement on Form S ‑1 that was declared effective on June 24, 2015. The IPO generated net proceeds of approximately $113.6 million, after deducting underwriting discounts and commissions of $8.7 million and other related expenses of approximately $1.9 million. At December 31, 2015, we had cash, cash equivalents and short-term investments of $91.1 million. We may seek to obtain additional financing in the future through the issuance of our common stock, through other equity or debt financings, through collaborations or partnerships with other companies or through non ‑dilutive financing. We may not be able to raise additional capital on terms acceptable to us, or at all, and any failure to raise capital as and when needed could materially harm our business, results of operations and future business prospects, including our ability to continue as a going concern. We believe that our existing cash, cash equivalents and short-term investments will be sufficient to fund our operations for at least the next 12 months .

Factors affecting future results

In January 2007, we entered into an agreement with GMP Vision Solutions Inc. , or GMP, to acquire certain in ‑process research and development and therein agreed to make periodic royalty payments to GMP. In December 2012, we paid GMP $1.0 million for a 90 ‑day option to buy out all of the remaining royalties payable to GMP under the January 2007 agreement. We did not exercise the option, which expired in April 2013.

In November 2013, we amended the agreement and entered into a royalty buyout agreement with GMP pursuant to which we bought out all of the remaining royalties payable to GMP in exchange for the issuance of an aggregate of $17.5 million in secured promissory notes payable to GMP and a party related to GMP. In connection with this buyout agreement, we recognized an intangible asset valued at $17.5 million, which is being amortized to cost of sales on a straight ‑line basis by year as follows: $0.5 million in 2013, $3.5 million in each of 2014, 2015, 2016 and 2017 and $3.0 million in 2018. The notes required monthly interest ‑only payments through December 31, 2014, followed by 24 equal monthly principal and interest payments of $0.8 million, which we began paying on January 31, 2015 and will pay through December 31, 2016. Accordingly, our cost of sales will be impacted through 2018 as a result of the amortization and our cash flows will be adversely affected by the debt service costs, primarily in 2015 and 2016 when principal payments are required in addition to interest. The terms of the subordinated notes are more fully described below under “—Liquidity and capital resources—indebtedness.”

In December 2014, we entered into an agreement with The Regents of the University of California, or University , to correct inventorship in connection with a group of our U.S. patent rights and to obtain from the University a covenant that it did not and would not claim any right or title to such patent rights and will not challenge or assist any others in challenging such patent rights. In connection with the agreement, we agreed to pay to the University the sum of $2.7 million in five payments during 2015 as follows: $500,000 by January 30, 2015; $125,000 by March 31, 2015; $250,000 by June 30, 2015; $250,000 by September 30, 2015; and $1,575,000 by December 31, 2015. Under the terms of the agreement, the payments were due within 60 days of our IPO, and, accordingly, we paid the balance due of $1,825,000 prior to August 29, 2015. We accrued the $2.7 million obligation, net of imputed interest of $0.1 million, as of December 31, 2014, and charged it to cost of sales in the year ended December 31, 2014. In addition, beginning with sales on or after January 1, 2015, we agreed to pay the University a payment equal to a low ‑single digit percentage of worldwide net sales of certain current and future products, including our *iStent* products, with a required minimum annual payment of $500,000. The ongoing royalty payment terminates on the date that the last of the patent rights expires, which is currently expected to be in 2022.

In February 2015, we and our primary bank executed an Amended and Restated Revolving Credit and Term Loan Agreement, or the Amended Credit Agreement, which provided for a $5.0 million senior secured term loan, a $5.0 million senior secured draw ‑to term loan and an $8.0 million senior secured revolving credit facility. The senior secured term loan and draw ‑to term loan would have matured and would have been required to be fully paid by February 23, 2019. On the closing date, we received $5.0 million cash under the senior secured term loan. The entire unpaid principal amount plus any accrued but unpaid interest under the revolving line of credit was due to become payable in full on February 23, 2017. As of July 31, 2015 we had drawn $2.0 million under the draw ‑to term loan. On July 31, 2015, we paid off all amounts outstanding under the Amended Credit Agreement with the payment of $7.0 million in principal plus all interest and fees payable through the payoff date, and recorded a loss on extinguishment

of debt in the amount of $0.2 million. The Amended Credit Agreement and all related security interests were terminated on July 31, 2015. The agreements with our primary bank are more fully described under "—Liquidity and capital resources—indebtedness."

Components of results of operations

Net sales

We operate in one reportable segment and substantially all of our net sales are derived from sales of our *iStent* products, net of customer returns and allowances. We recognize net sales when goods are shipped, title and risk of loss transfer to our customers, persuasive evidence of an arrangement exists and collectability is reasonably assured.

We sell our products through a direct sales organization in the United States, and outside the United States we sell our products primarily through independent distributors and through direct sales subsidiaries in some countries . The primary end ‑user customers for our products are hospitals and surgery centers.

We anticipate our net sales will 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. We also expect that our net sales within a fiscal year may be impacted seasonally and reflect seasonality patterns generally consistent with U.S. cataract procedure volumes, which are typically softer in the first quarter and stronger in the fourth quarter of a given year .

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* products at our headquarters in Laguna Hills, California using components manufactured by third parties. Due to the relatively low production volumes of our *iStent* products, 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.

Beginning in late 2013, cost of sales has included amortization of the $17.5 million intangible asset we recognized in connection with our royalty buyout agreement with GMP in November 2013. The amortization expense was $3.5 million, $3.5 million and $0.5 million in the years ended December 31, 2015, 2014 and 2013 and is estimated to be $3.5 million in each of 2016 and 2017, and $3.0 million in 2018.

Beginning in 2015, cost of sales includes a charge equal to a low single ‑digit percentage of worldwide net sales of certain current and future products, including our *iStent* products, with a required minimum annual payment of $500,000, which amount became payable to the University in connection with our December 2014 agreement. This obligation will expire upon the expiration of the last to expire of the patent rights that are the subject of the December 2014 agreement, which is currently expected to be in 2022. Additionally, as a medical device manufacturer, we are required to pay the 2.3% federal medical device excise tax on U.S. sales of medical devices manufactured by us. Under the PATH Act, this tax has been suspended from January 1, 2016, to December 31, 2017, and, absent further legislative action, will be reinstated starting January 1, 2018. The medical device excise tax is included in our cost of sales in 2015, 2014 and 2013 .

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 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 the aforementioned intangible asset amortization, expense related to our agreement with the University . We also expect our gross margin to be favorably

impacted by the Consolidated Appropriations Act of 2016 moratorium for 2016 and 2017 on the medical device excise tax.

Selling, general and administrative

Our selling, general and administrative, or 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, business development and administrative functions. Other significant SG&A expenses include marketing programs, advertising, conferences and congresses, and travel expenses, as well as the costs associated with obtaining and maintaining our patent portfolio, professional fees for accounting, auditing, consulting and legal services, travel and allocated overhead expenses.

We expect SG&A expenses to continue to grow as we increase our sales and marketing infrastructure globally and our clinical education and general administration infrastructure in the United States. We also expect other nonemployee ‑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. In addition, we have begun to incur increased SG&A expenses resulting from becoming a public company, which may further increase when we are no longer able to rely on certain “emerging growth company” exemptions we are afforded under the Jumpstart Our Business Startups Act, or the JOBS Act.

Research and development

Our research and development, or R&D, activities primarily consist of new product development projects, pre ‑clinical studies, IDE 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; 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 increase as we initiate and advance our development programs, the most costly of which are expected to be our *iStent Inject* , *iStent Supra* and *iDose* product candidates.

Completion dates and costs for our clinical development programs including seeking regulatory approvals, and our research programs can 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, as well as ongoing assessments as to each current or future product candidate’s commercial potential and our likelihood of obtaining necessary regulatory approvals.

Other (expense) income, net

Other (expense) income, net primarily consists of interest expense on our Amended Credit Agreement and our secured promissory notes payable to GMP and a party related to GMP as well as changes in the fair value of our stock warrant liability. On July 31, 2015, we paid off in full all amounts outstanding under the Amended Credit Agreement and terminated the agreement, and recorded a loss on extinguishment of debt in other (expense) income. In 2015, other (expense) income also included the loss on deconsolidation of DOSE .

Results of operations

Comparison of years ended December 31, 2015 and 2014

(dollars in thousands)	2015	Year ended December 31, 2014	% Increase (decrease)
Statements of operations data:			
Net sales	$ 71,700	$ 45,587	57 %
Cost of sales	12,988	11,418	14 %
Gross profit	58,712	34,169	72 %
Operating expenses:			
Selling, general and administrative	43,961	28,135	56 %
Research and development	25,047	19,205	30 %
Total operating expenses	69,008	47,340	46 %
Loss from operations	(10,296)	(13,171)	(22)%
Loss on deconsolidation of DOSE	(25,685)	—	Nm
Total other (expense) income, net	(2,307)	(868)	166 %
Provision for income taxes	33	18	83 %
Net loss	$ (38,321)	$ (14,057)	173 %

Net sales

Net sales for the years ended December 31, 2015 and 2014 were $71.7 million and $45.6 million, respectively, reflecting an increase of $26.1 million or 57%, with net sales in the United States representing $67.7 million and $42.9 million of net sales, respectively, and accounting for 95% of the overall increase. Our average number of domestic sales representatives increased to 45 for the year ended December 31, 2015 from 35 for the year ended December 31, 2014. The higher number of sales representatives helped increase our customer base, leading to growth in unit sales. Increased unit volume was responsible for the majority of the increase in net sales .

Cost of sales

Cost of sales for the years ended December 31, 2015 and 2014 were $13.0 million and $11.4 million, respectively, reflecting an increase of $1.6 million or 14%. Our gross margin for the year ended December 31, 2015 was approximately 82% compared to approximately 75% in 2014. In 2014, cost of sales included a charge of $2.6 million, or 6% of 2014 sales, associated with our December 2014 agreement with the University , which accounted for the majority of the improvement in our gross margin .

Selling, general and administrative expenses

SG&A expenses for the years ended December 31, 2015 and 2014 were $44.0 million and $28.1 million, respectively, reflecting an increase of $15.9 million or 56%. Stock -based compensation expense increased by $4.7 million, which included a charge of $2.8 million for the recording of cumulative stock -based compensation expense associated with stock options we granted in July 2014 containing a performance condition that was satisfied upon the completion of our IPO. The remaining increase in SG&A expenses was primarily the result of an increase of approximately $4.6 million in personnel, travel and other costs associated with our expanding domestic sales force; an increase of approximately $2.3 million for additional administrative and marketing personnel; an increase of approximately $2.1 million in legal fees primarily associated with our patent litigation; and an increase in SG&A expenses incurred by our foreign subsidiaries of approximately $1.2 million .

Research and development expenses

R&D expenses for the years ended December 31, 2015 and 2014 were $25.0 million and $19.2 million, respectively, reflecting an increase of $5.8 million or 30%. Payroll and related expenses increased by approximately

$3.2 million due to the cost of additional personnel, primarily in our clinical affairs function, required to manage the increased number of clinical studies and associated investigational sites and study investigators. Stock -based compensation expense increased by $1.5 million, which included a charge of $0.9 million for the recording of cumulative stock -based compensation expense associated with stock options we granted in July 2014 containing a performance condition that was satisfied upon the completion of our IPO. The remaining increase in R&D expenses resulted primarily from higher clinical study costs, which included payments to investigational sites and study investigators, consultants, and other outside technical service providers and the costs of related materials, supplies and travel .

Other (expense) income, net

We recorded other expense, net for the years ended December 31, 2015 and 2014 of approximately $28.0 million and $0.9 million, respectively, reflecting an increase of $27.1 million. The 2015 period includes a charge of $25.7 million incurred with the deconsolidation of the non -glaucoma related assets of DOSE and elimination of the noncontrolling interest. See "— Critical accounting policies and significant estimates—DOSE—variable interest entity accounting ."

Comparison of years ended December 31, 2014 and 2013

(dollars in thousands)	Year ended December 31, 2014	2013	% Increase (decrease)
Statements of operations data:			
Net sales	$ 45,587	$ 20,946	118 %
Cost of sales	11,418	2,535	350 %
Gross profit	34,169	18,411	86 %
Operating expenses:			
Selling, general and administrative	28,135	17,098	65 %
Research and development	19,205	15,511	24 %
Total operating expenses	47,340	32,609	45 %
Loss from operations	(13,171)	(14,198)	(7)%
Total other expense, net	(868)	(23)	3,674 %
Provision for income taxes	18	6	200 %
Net loss	$ (14,057)	$ (14,227)	(1)%

Net sales

Net sales for the years ended December 31, 2014 and 2013 were $45.6 million and $20.9 million, respectively, reflecting an increase of $24.7 million or 118%, with net sales in the United States representing $42.9 million and $19.5 million, respectively, and accounting for 95% of the increase. The increase in net sales was primarily attributable to an increase in the number of sales representatives and increased reimbursement coverage, which together led to an increase in unit sales growth. Our average number of sales representatives increased to 35 in 2014 from 22 in 2013. Increased unit volume accounted for approximately 98% of the increase in net sales, and approximately 2% of the increase in net sales resulted from an increase in average selling prices.

Cost of sales

Cost of sales for the years ended December 31, 2014 and 2013 were $11.4 million and $2.5 million, respectively, reflecting an increase of $8.9 million or 350%. Our gross margin for the year ended December 31, 2014 was approximately 75% compared to approximately 88% in the same period of 2013. Cost of sales in 2014 includes a $2.6 million charge associated with our December 2014 agreement with the University and $3.5 million of intangible asset amortization, which together totaled $6.1 million or approximately 13% of 2014 net sales. Amortization of the intangible asset commenced late in 2013 and $0.5 million was recorded in cost of sales for the year ended December 31, 2013, representing less than 3% of 2013 net sales. The increase in intangible asset amortization and the charge associated

with the University agreement together account for 11% of the 13% reduction in gross margin for the year ended December 31, 2014 as compared to the year ended December 31, 2013.

Selling, general and administrative expenses

SG&A expenses for the years ended December 31, 2014 and 2013 were $28.1 million and $17.1 million, respectively, reflecting an increase of $11.0 million or 65%. The increase in SG&A expenses was primarily the result of an increase of approximately $4.4 million in personnel, travel and other costs associated with our expanding domestic sales force; an increase of approximately $1.9 million in legal fees primarily associated with our patent litigation; an increase of approximately $1.2 million in SG&A expenses incurred by our subsidiary in Germany; and approximately $1.2 million in costs in 2014 related to our efforts to prepare for our initial public offering.

Research and development expenses

R&D expenses for the years ended December 31, 2014 and 2013 were $19.2 million and $15.5 million, respectively, reflecting an increase of $3.7 million or 24%. The increase resulted primarily from higher clinical study costs, which included payments to investigational sites and investigators, consultants, and other outside technical service providers and the costs of related materials, supplies and travel. Our *iStent I nject* clinical study enrolled significantly more subjects in 2014 as compared to 2013, and was the largest single contributor to the expense increase.

Other expense, net

We recorded other expense, net for the years ended December 31, 2014 and 2013 of approximately $0.9 million and $23,000, respectively. The increase was primarily the result of interest expense on our subordinated debt issued in November 2013.

Liquidity and capital resources

Since our inception, we have incurred losses and negative cash flow from our operations and, as of December 31, 2015, we had an accumulated deficit of approximately $ 196.6 million. We have funded our operations to date from the sale of equity securities, issuance of notes payable, cash exercises of stock options and warrants to purchase equity securities and cash generated from net sales, and on June 30, 2015, we completed our IPO, selling 6.9 million newly issued shares of common stock at $18.00 per share, which raised net proceeds of approximately $113.6 million, after deducting underwriting discounts and commissions of $8.7 million and other related expenses of approximately $1.9 million. We have made and expect to continue to make significant investments in our global sales force and marketing programs. Costs for FDA ‑approved IDE studies in our industry are expensive as are the costs to develop new products, and we have begun to incur a significant increase in administrative costs as we operate as a public company. We expect to invest significantly more resources into our business using proceeds from the IPO. Accordingly, we expect to continue to experience net losses for the foreseeable future and expect that our sales performance will significantly impact our cash management decisions.

At December 31, 2015, we had $ 91.1 million in cash , cash equivalents and short-term investments . We believe that our available cash, cash equivalents, investment balances and interest we earn on these balances and cash generated from sales of our *iStent* products will be sufficient to satisfy our liquidity requirements for at least the next 12 months.

Cash flows

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

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

(amounts in millions)	Year ended December 31, 2015	2014	2013
Net cash provided by (used in):			
Operating activities	$ (2.2)	$ (7.1)	$ (13.3)
Investing activities	(85.6)	(0.9)	(1.0)
Financing activities	107.1	3.5	19.3
Exchange rate changes	—	0.1	—
Net increase (decrease) in cash and cash equivalents	$ 19.3	$ (4.4)	$ 5.0

At December 31, 2015, our cash , cash equivalents and sh o rt-term investments 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 years ended December 31, 2015, 2014 and 2013, we used $ 2.2 million, $7.1 million and $13.3 million, respectively, of net cash in operating activities. The decrease in net cash used in operating activities primarily reflects an increase in cash generated from significantly higher net sales of our *iStent* partially offset by increases in our total operating expenses. For the year ended December 31, 2015, the total net change in operating assets and liabilities reflected cash usage of $ 3.4 million due to increases in accounts receivable and inventory, partially offset by an increase in accounts payable. All other adjustments to reconcile net loss to net cash used in operating activities totaled $ 39.5 million, primarily consisting of the $25.7 million loss on the deconsolidation of DOSE. The remaining adjustments primarily consisted of stock -based compensation expense of $ 7.9 million and depreciation and amortization of $ 4.3 million. For the year ended December 31, 2014, the total net change in operating assets and liabilities provided cash of $1.2 million, as growth in accounts payable and accrued liabilities exceeded the combined growth in accounts receivable and inventory. Additionally, net non -cash operating costs totaled $5.7 million. For the year ended December 31, 2013, the total net change in operating assets and liabilities used cash of $1.4 million due to increases in accounts receivable and inventory, partially offset by an increase in accounts payable. More than offsetting this amount were net non -cash operating costs totaling $2.4 million, primarily consisting of depreciation and amortization and stock -based compensation expense.

Investing activities

In the years ended December 31, 2015, 2014 and 2013, we used approximately $85.6 million, $0.9 million and $1.0 million, respectively, of net cash in investing activities; cash used for purchases of property and equipment was approximately $0.9 million, $0.9 million and $1.0 million, respectively. In the year ended December 31, 2015, we used approximately $69.8 million for purchases of short-term investments, and we used $15.0 million for the purchase of the *iDOSE* product line from DOSE .

We expect to increase our investment in property and equipment in the future as we expand 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, 2015, 2014 and 2013, cash of $107.1 million, $3.5 million and $19.3 million, respectively, was provided from financing activities. In the year ended December 31, 2015, we received net cash proceeds of approximately $113.6 million from our IPO; approximately $6.9 million in net proceeds from senior secured term and draw-to term loans; and approximately $3. 3 million from the exercises of stock options and warrants and purchases of our common stock by employees pursuant to our Employee Stock Purchase Plan. In the year ended

December 31, 2015, we used approximately $7.8 million for note payments; $7.0 million to pay off and fully retire the senior secured term and draw-to term loans; and $1.9 million in net payments on the line of credit .

In the ye ar ended December 31, 2014, we received net proceeds of $1.9 million under our line of credit and we received proceeds of $0. 8 million and $0. 9 million from the exercises of stock options and preferred stock warrants, respectively. In the year ended December 31, 2013, we raised $19.2 million from the issuance of Series F convertible preferred stock.

Indebtedness

Notes payable to GMP Vision Solutions

In November 2013, we amended the agreement originally entered into with GMP in January 2007 and executed a royalty buyout agreement with GMP pursuant to which we issued an aggregate of $17.5 million in secured promissory notes to GMP and a party related to GMP in exchange for the cancellation of remaining royalties payable to GMP under the original agreement. These notes are secured by all of our assets, excluding intellectual property, and were previously subordinate to the rights of our bank lender in connection with our Amended Credit Agreement, described below prior to the repayment in full of that facility. The notes carry an interest rate of 5% per annum and required monthly interest -only payments from November 30, 2013 through December 31, 2014 of $72,900, followed by 24 equal monthly principal and interest payments of $0.8 million, which we began paying on January 31, 2015 and will pay through December 31, 2016. We concluded that the transaction resulted in the recognition of a $17.5 million intangible asset. After determining that the pattern of future cash flows associated with this intangible asset could not be reliably estimated with a high level of precision, we concluded that the intangible asset will be amortized to cost of sales in our statements of operations on a straight line basis over the estimated useful life of five years.

In the years ended December 31, 2015, 2014 and 2013, we recorded related amortization expense of $3.5 million, $3.5 million and $0.5 million, respectively, in cost of sales. Estimated amortization expense will be $3.5 million in each of 2016 and 2017, and $3.0 million in 2018.

Amended and Restated Revolving Credit and Term Loan Agreement

In June 2013, we entered into a loan and security agreement, or Credit Agreement, with our primary bank for a line of credit in the maximum principal amount of $6.0 million. Advances under the Credit Agreement were limited to the lesser of (i) $6.0 million or (ii) 77% of the sum of cash, cash equivalents and eligible domestic accounts receivable. The entire unpaid principal amount plus any accrued but unpaid interest was due to become payable in full on June 5, 2015. Obligations under the line of credit bore interest on the outstanding daily balance thereof at the bank's prime rate plus 0.5% (3.75% at December 31, 2014). Amounts owed were secured by a first priority security interest in all of our assets, excluding intellectual property. Additionally, the terms of the Credit Agreement contained various affirmative and negative covenants. There was $1.9 million outstanding under this line of credit as of December 31, 2014.

In February 2015, we and our primary bank executed the Amended Credit Agreement, which provided for a $5.0 million senior secured term loan, a $5.0 million senior secured draw -to term loan and an $8.0 million senior secured revolving credit facility. Amounts owed under the Amended Credit Agreement were secured by a first priority security interest in all of our assets, excluding intellectual property. We were required to comply with certain non -financial and financial covenants as provided in the Amended Credit Agreement that, if not met, could have constituted events of default. We were in compliance with all such covenants through the payoff date.

On the closing date, we received $5.0 million cash under the senior secured term loan and immediately paid off the $2.1 million balance outstanding under the line of credit. This loan required quarterly principal payments of $0.4 million over a three -year period beginning May 1, 2016 and was to mature February 23, 2019. The senior secured draw -to term loan was to be available through February 23, 2016 for advances up to an aggregate of $5.0 million, and required quarterly principal payments equal to 1/12 of the aggregate principal amount over a three -year period beginning May 1, 2016 and was to mature February 23, 2019. Prior to our repayment of the term loan described below, we had drawn $2.0 million under the draw -to term loan. Advances under the revolving line of credit were limited to the lesser of

(i) $8.0 million or (ii) a calculated borrowing base consisting of (a) 80% of eligible accounts receivable plus (b) the lesser of 30% of eligible inventory or $1.5 million. The entire unpaid principal amount plus any accrued but unpaid interest under the revolving line of credit was due to become payable in full on February 23, 2017.

Outstanding balances under the senior secured term loan and senior secured draw ‑to term loan bore interest on the outstanding daily balance thereof at an annual percentage rate equal to the bank's prime rate plus 2%. At our option, all or a portion of the amounts owed under any of the senior secured term loan and draw ‑to term loan may have been converted into Eurodollar ‑based advances at an annual percentage rate equal to LIBOR plus 3%. Outstanding balances under the revolving credit facility bore interest on the outstanding daily balance thereof at an annual percentage rate equal to the bank's prime rate plus 1.75%. At our option, all or a portion of the amounts owed under the revolving credit facility may have been converted into Eurodollar ‑based advances at an annual percentage rate equal to LIBOR plus 2.75%. In connection with the execution of the Amended Credit Agreement, we issued warrants to the lenders to purchase an aggregate of 11,298 shares of common stock at an exercise price of $8.85 per share.

On July 31, 2015, we paid off in full all amounts outstanding under the Amended Credit Agreement with the payment of $7.0 million in principal plus all interest and fees payable through the payoff date and recorded a loss on extinguishment of debt in the amount of $0.2 million. The Amended Credit Agreement and all related security interests were terminated on July 31, 2015. Accordingly, this facility is no longer outstanding and available to us.

There were no material commitments for capital expenditures as of December 31, 2015.

Contractual obligations

The following table summarizes our significant contractual obligations as of December 31, 2015 and the effect those obligations are expected to have on our liquidity and cash flows in future periods.

	Payments due by period				
Contractual obligations (in millions)	**Total**	**Less than 1 year**	**1 - 3 years**	**3 - 5 years**	**More than 5 years**
Operating lease obligations	$ 3,352	$ 585	$ 1,020	$ 1,151	$ 596
Long-term debt obligations, excluding interest	9,696	8,931	765	—	—
Total contractual obligations	$ 13,048	$ 9,516	$ 1,785	$ 1,151	$ 596

Off ‑balance sheet arrangements

We do not have any off ‑balance sheet arrangements as defined in the rules and regulations of the SEC. We do not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off ‑balance sheet arrangements or for any other contractually narrow or limited purpose. However, from time to time we enter into certain types of contracts that contingently require us to indemnify parties against third ‑party claims including in connection with certain real estate leases, and supply purchase agreements, and with directors and officers. The terms of such obligations vary by contract and in most instances a maximum dollar amount is not explicitly stated therein. Generally, amounts under these contracts cannot by reasonably estimated until a specific claim is asserted, thus no liabilities have been recorded for these obligations on our balance sheets for any of the periods presented.

Inflation

We may experience pressure on our *iStent* selling prices resulting from potential future reductions in reimbursement payments to our customers, particularly from governmental payors such as Medicare or Medicaid but also from private payors. We could also be impacted by risi ng costs for certain inflation ‑ sensitive operating expenses such as labor and employee benefits. However, we do not believe that inflation has had a material effect on our business, financial condition or results of operations presented herein. If our costs were to become subject to significant

inflationary pressures, we may not be able to fully offset such higher costs through selling price increases. Our inability or failure to do so could adversely affect our business, financial condition and results of operations.

Critical accounting policies and significant estimates

Management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP. The preparation of these 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 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 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 generate revenue primarily from sales of our *iStent* products. We recognize revenue from product sales when the following criteria are met: goods are shipped, title and risk of loss has transferred to our customers, persuasive evidence of an arrangement exists and collectability is reasonably assured. Persuasive evidence of an arrangement exists when we have a contractual arrangement in place with the customer. Delivery has occurred when a product is shipped. If persuasive evidence of an arrangement exists and delivery has occurred, we determine whether the invoiced amount is fixed or determinable and collectability of the invoiced amount is reasonably assured. We assess whether the invoiced amount is fixed or determinable based on the existing arrangement with the customer, including whether we have sufficient history with a customer to reliably estimate the customer's payment patterns. We assess collectability by evaluating historical cash receipts and individual customer outstanding balances. To the extent all criteria set forth above are not satisfied at the time of shipment, revenue is recognized when cash is received from the customer.

We permit returns of product if such product is returned in good condition and from normal distribution channels. Estimated allowances for sales returns are based upon the historical patterns of our product returns matched against sales, and our evaluation of specific factors that may increase the risk of product returns. Product returns to date have been immaterial.

Clinical trial expense accruals

As part of our R&D expenses, we accrue at each balance sheet date the estimated costs of clinical study activities performed by third -party clinical sites with whom we have agreements providing for fees based upon the quantities of subjects enrolled and clinical evaluation visits that occur over the life of the study. The 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 us at each financial reporting date. If the actual timing of performance of activities varies from the assumptions used in the estimates, we adjust the accruals accordingly. There have been no material adjustments to our prior period accrued estimates for clinical trial activities through December 31, 2015. If we underestimate or overestimate the activity or fees associated with a study or service at a given point in time, adjustments to R&D expenses may be necessary in future periods. Subsequent changes in estimates may result in a material change in our accruals. Nonrefundable advance payments for goods and services, including fees for process development or manufacturing and distribution of clinical supplies that will be used in future research and development activities, are deferred and recognized as expense in the period that the related goods are consumed or services are performed.

Inventory valuation

We value inventory at the lower of cost or market (net realizable value). Cost is determined by the first -in, first -out method. This policy requires us to make estimates regarding the market value of our inventory, including an assessment of excess or obsolete inventory. We evaluate inventory for excess quantities and obsolescence based on an estimate of the future demand for our product within a specified time horizon, and record an allowance to reduce the carrying value of inventory as determined necessary. The estimates we use for demand are also used for near -term capacity planning and inventory purchasing and are consistent with our revenue forecasts. If our actual demand is less than our forecast demand, we may be required to take additional excess inventory charges, which would decrease gross margin and adversely impact net operating results in the future.

Stock -based compensation expense

Stock -based compensation expense is measured at the date of grant, based on the estimated fair value of the award using the Black -Scholes option pricing model. For awards subject to time -based vesting conditions, we recognize stock - based compensation expense over the employee's requisite service period on a straight -line basis, net of estimated for feitures. We account for stock - based compensation arrangements with non -employees using a fair value approach. Stock options granted to non -employees are subject to periodic revaluation over their vesting terms.

The estimation of the fair value of each stock -based grant or issuance on the date of grant involves numerous assumptions by management. Although we calculate the fair value under the Black -Scholes option pricing model, which is a standard option pricing model, this model still requires the use of numerous assumptions, including, among others, the expected life (turnover), volatility of the underlying equity security, a risk free interest rate and expected dividends. We do not have publicly traded equity and have a limited operating history and a lack of company -specific historical and implied volatility data, and therefore we have estimated stock price volatility based upon an index of the historical volatilities of a group of four publicly -traded medical device peer companies. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available. We have estimated the expected term of our employee stock options using the "simplified" method, whereby the expected life equals the average of the vesting term and the original contractual term of the option. The model and assumptions also attempt to account for changing employee behavior as the stock price changes and capture the observed pattern of increasing rates of exercise as the stock price increases. The use of different values by management in connection with these assumptions in the Black -Scholes option pricing model could produce substantially different results.

The assumptions used in the Black -Scholes option pricing model are as follows:

	Year ended December 31,		
	2015	**2014**	**2013**
Risk-free interest rate	1.79 %	1.91 %	1.25 %
Expected dividend yield	0.0 %	0.0 %	0.0 %
Expected volatility	56.3 %	60.7 %	63.1 %
Expected term (in years)	6.30	6.14	6.07

In July 2014, we granted stock options to purchase an aggregate of 1.2 million shares of common stock, which options contain a performance condition such that they only become exercisable in the event that our common stock is listed on a national securities exchange within one year from the date of grant. In accordance with authoritative guidance, we did not record any compensation expense associated with the grants until the performance condition was satisfied in the three month period ended June 30, 2015. Upon the completion of the IPO on June 30, 2015, we immediately recognized cumulative compensation cost of $3.8 million for the grants as if the method had been applied since the date of grant using the required graded accelerated attribution method, and we will record compensation expense over the remainder of the four -year vesting period using this method. Stock options granted subsequent to July 2014 do not contain a performance condition.

DOSE—variable interest entity accounting

In October 2009, we formed a wholly -owned subsidiary, DOSE, and in April 2010, we distributed all of our shares of common stock of DOSE via a stock dividend to our stockholders of record as of the close of business on March 31, 2010. Since its formation, we provided DOSE with a small number of leased employees, management services and space, all of which had been charged to DOSE pursuant to written agreements between the parties. Additionally, we provided DOSE the cash required to fund its operations that, together with accrued interest and charges for the aforementioned services, we had recorded in an intercompany receivable account. Up until the transaction on June 30, 2015 described below, we had accounted for DOSE as a variable interest entity in which we had a variable interest in all reporting periods since the formation of DOSE. Accordingly, our consolidated financial statements include the accounts of DOSE, with all intercompany balances eliminated and with the deficit balance of DOSE's net assets reflected as noncontrolling interest, up to but excluding June 30, 2015.

On June 30, 2015, we completed a transaction initially executed in July 2014, the closing of which was contingent upon the successful completion of an IPO. Pursuant to the terms of the asset purchase agreement, we acquired from DOSE certain assets, including the *iDose* product line, in exchange for a payment of $15.0 million in cash and the elimination of the $10.9 million intercompany receivable owed to us by DOSE as of the closing date. In addition to the asset purchase agreement, the parties agreed to an amended and restated patent license agreement and an amended and restated transition services agreement that provides for limited support to DOSE for a period of up to three years. Either we or DOSE can terminate the transition services agreement upon adequate written notice. Two members of our board of directors currently serve as the board of directors of DOSE.

We reconsidered our relationship with DOSE as a result of the transaction and determined we are no longer considered to be the primary beneficiary with the power to direct operations and the right to receive benefits/absorb losses of DOSE; therefore, upon the closing of the transaction on June 30, 2015, we derecognized DOSE and no longer consider it a consolidated entity in our financial statements. Accordingly, in the three months ended June 30, 2015, we recorded a charge to other expense in the amount of $25.7 million to reflect the deconsolidation of DOSE's non -glaucoma related assets and noncontrolling interest.

See Note 12 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for more information regarding the carrying amount and classification of DOSE's assets and liabilities that are included in o ur consolidated balance sheets.

The list above is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by GAAP. There are also areas in which our management's judgment in selecting any available alternative may produce a materially different result. Please see our audited consolidated financial statements and notes thereto included elsewhere in this Annual Report on Form 10-k , which contain accounting policies and other disclosures required by GAAP.

Recent Accounting Pronouncements

For a description of recent accounting pronouncements, see the notes to our consolidated financial statements.

ITEM 7 A . 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 a certificate 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 the Company. As of December 31, 2015, we had an aggregate of $9.7 million in long-term debt, which is comprised of our secured promissory notes to GMP and a party related to GMP. The interest rate on these notes is fixed and we have no variable interest rate debt outstanding. If overall interest rates had increased by 10% during the periods presented, our interest expense would not have been materially affected. We do not believe that our cash or

cash equivalents have significant risk of default or illiquidity. 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

Net sales to our distributors in Europe are denominated in Euros and the financial statements of our foreign subsidiaries and their sales to customers, are denominated in the foreign subsidiaries' respective functional currencies, and therefore we have exposure to foreign currency exchange rates. The remainder of our business is primarily denominated in U.S. dollars. The effect of a 10% adverse change in exchange rates on foreign denominated cash, receivables and payables would not have been material for the periods presented. As our operations in countries outside of the United States grow, our results of operations and cash flows will be subject to fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future. To date, we have not entered into any material foreign currency hedging contracts although we may do so in the future.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DAT A

Index to consolidated financial statements

Report of independent registered public accounting firm

The Board of Directors and Stockholders of
Glaukos Corporation

We have audited the accompanying consolidated balance sheets of Glaukos Corporation as of December 31, 2015 and 2014, and the related consolidated statements of operations, comprehensive loss, convertible preferred stock and stockholders' equity (deficit) , and cash flows for each of the three years in the period ended December 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Glaukos Corporation at December 31, 201 5 and 201 4 , and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Irvine, California
March 14 , 2016

Glaukos Corporation
Consolidated balance sheets
(in thousands, except par values)

	December 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 21,572	$ 2,304
Short-term investments	69,552	—
Accounts receivable, net	7,549	5,398
Inventory	4,097	2,258
Prepaid expenses and other current assets	1,290	534
Restricted cash	80	60
Total current assets	104,140	10,554
Property and equipment, net	2,154	1,950
Intangible assets, net	10,218	13,475
Deposits and other assets	149	42
Total assets	$ 116,661	$ 26,021
Liabilities, convertible preferred stock and equity (deficit)		
Current liabilities:		
Accounts payable	$ 3,626	$ 3,298
Accrued liabilities	7,793	6,462
Line of credit	—	1,850
Long-term debt, current portion	8,931	8,532
Deferred rent	12	45
Total current liabilities	20,362	20,187
Long-term debt, less current portion	765	8,968
Stock warrant liability	105	379
Other liabilities	238	12
Total liabilities	21,470	29,546
Commitments and contingencies		
Convertible preferred stock (see Note 8)	—	157,379
Stockholders' equity (deficit):		
Preferred stock, $0.001 par value; 5,000 shares and no shares authorized at December 31, 2015 and 2014; no shares issued and outstanding at December 31, 2015 and 2014	—	—
Common stock, $0.001 par value; 150,000 shares and 77,000 authorized at December 31, 2015 and 2014, respectively; 32,209 and 2,470 shares issued and 32,181 and 2,442 shares outstanding at December 31, 2015 and 2014, respectively	32	6
Additional paid-in capital	291,853	8,155
Accumulated other comprehensive income	51	44
Accumulated deficit	(196,613)	(159,372)
	95,323	(151,167)
Less treasury stock (28 shares as of December 31, 2015 and 2014)	(132)	(132)
Total stockholders' equity (deficit)	95,191	(151,299)
Noncontrolling interest	—	(9,605)
Total equity (deficit)	95,191	(160,904)
Total liabilities, convertible preferred stock and equity (deficit)	$ 116,661	$ 26,021

Glaukos Corporation
Consolidated statements of operations
(in thousands, except per share amounts)

	Year ended December 31,		
	2015	2014	2013
Net sales	$ 71,700	$ 45,587	$ 20,946
Cost of sales	12,988	11,418	2,535
Gross profit	58,712	34,169	18,411
Operating expenses:			
Selling, general and administrative	43,961	28,135	17,098
Research and development	25,047	19,205	15,511
Total operating expenses	69,008	47,340	32,609
Loss from operations	(10,296)	(13,171)	(14,198)
Other income (expense), net			
Interest income	82	3	13
Loss on deconsolidation of DOSE	(25,685)	—	—
Loss on extinguishment of debt	(195)	—	—
Interest and other expense, net	(1,062)	(876)	(307)
Change in fair value of stock warrant liability	(1,132)	5	271
Total other income (expense), net	(27,992)	(868)	(23)
Loss before taxes	(38,288)	(14,039)	(14,221)
Provision for income taxes	33	18	6
Net loss	(38,321)	(14,057)	(14,227)
Net loss attributable to noncontrolling interest	(1,080)	(1,931)	(1,588)
Net loss attributable to Glaukos Corporation	$ (37,241)	$ (12,126)	$ (12,639)
Net loss per share, basic and diluted, attributable to Glaukos Corporation stockholders	$ (2.13)	$ (5.29)	$ (6.21)
Weighted-average shares used to compute basic and diluted net loss per share attributable to Glaukos Corporation stockholders	17,474	2,294	2,036

Glaukos Corporation
Consolidated statements of comprehensive loss
(in thousands)

	Year ended December 31,		
	2015	2014	2013
Net loss	$ (38,321)	$ (14,057)	$ (14,227)
Other comprehensive income:			
Foreign currency translation adjustments	155	42	2
Unrealized loss on short-term investments, net of tax	(148)	—	—
Other comprehensive income	7	42	2
Total comprehensive loss	(38,314)	(14,015)	(14,225)
Comprehensive loss attributable to noncontrolling interest	(1,080)	(1,931)	(1,588)
Comprehensive loss attributable to Glaukos Corporation	$ (37,234)	$ (12,084)	$ (12,637)

Glaukos Corporation
Consolidated statements of convertible preferred stock and stockholders' equity (deficit)
(in thousands, except per share amounts)

	Convertible preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive income	Accumulated deficit	Treasury stock		Non-controlling interest	Total equity (deficit)
	Shares	Amount	Shares	Amount				Shares	Amount		
Balance at December 31, 2012	18,118	$ 126,210	2,004	$ 5	$ 4,555	$ —	$ (134,607)	—	$ —	$ (6,157)	$ (136,204)
Issuance of Series F convertible preferred stock at $8.85 per share	2,173	19,227	—	—	—	—	—	—	—	—	—
Conversion of convertible notes payable and accrued interest into Series F convertible preferred stock at $8.85 per share	1,217	10,773	—	—	—	—	—	—	—	—	—
Common stock issued under stock plans	—	—	118	—	172	—	—	—	—	1	173
Share-based compensation	—	—	—	—	1,346	—	—	—	—	—	1,346
Other comprehensive income	—	—	—	—	—	2	—	—	—	—	2
Net loss	—	—	—	—	—	—	(12,639)	—	—	(1,588)	(14,227)
Purchase of treasury stock	—	—	—	—	—	—	—	(28)	(132)	—	(132)
Balance at December 31, 2013	21,508	$ 156,210	2,122	$ 5	$ 6,073	$ 2	$ (147,246)	(28)	$ (132)	$ (7,744)	$ (149,042)
Issuance of Series C convertible preferred stock at $8.00 per share in connection with exercises of preferred stock warrants	105	836	—	—	—	—	—	—	—	—	—
Issuance of Series D convertible preferred stock at $11.38 per share in connection with exercises of preferred stock warrants	29	333	—	—	—	—	—	—	—	—	—
Common stock issued under stock plans	—	—	348	1	552	—	—	—	—	70	623
Share-based compensation	—	—	—	—	1,530	—	—	—	—	—	1,530
Other comprehensive income	—	—	—	—	—	42	—	—	—	—	42
Net loss	—	—	—	—	—	—	(12,126)	—	—	(1,931)	(14,057)
Balance at December 31, 2014	21,642	$ 157,379	2,470	$ 6	$ 8,155	$ 44	$ (159,372)	(28)	$ (132)	$ (9,605)	$ (160,904)
Issuance of Series D convertible preferred stock at $18.00 per share in connection with exercises of preferred stock warrants	94	1,698	—	—	—	—	—	—	—	—	—
Conversion of preferred stock into common stock	(21,736)	(159,077)	21,736	17	159,060	—	—	—	—	—	159,077
Issuance of common stock in initial public offering	—	—	6,900	7	113,582	—	—	—	—	—	113,589
Common stock issued under stock plans	—	—	1,097	2	2,979	—	—	—	—	—	2,981
Exercise of common stock warrant	—	—	6	—	188	—	—	—	—	—	188
Share-based compensation	—	—	—	—	7,889	—	—	—	—	—	7,889
Other comprehensive income	—	—	—	—	—	7	—	—	—	—	7
Net loss	—	—	—	—	—	—	(37,241)	—	—	(1,080)	(38,321)
Deconsolidation of DOSE	—	—	—	—	—	—	—	—	—	10,685	10,685
Balance at December 31, 2015	—	$ —	32,209	$ 32	$ 291,853	$ 51	$ (196,613)	(28)	$ (132)	$ —	$ 95,191

Glaukos Corporation
Consolidated statements of cash flow s
(in thousands)

	Year ended December 31,		
	2015	2014	2013
Operating Activities			
Net loss	$ (38,321)	$ (14,057)	$ (14,227)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	4,267	4,231	1,157
Stock-based compensation	7,889	1,530	1,346
Loss on deconsolidation of DOSE	25,685	—	—
Loss on extinguishment of debt	186	—	—
Change in fair value of stock warrant liability	1,132	(5)	(271)
Unrealized losses on intercompany loans	192	—	—
Accrued interest expense	—	—	44
Amortization of premium on short-term investments	51	—	106
Amortization of debt discount and deferred financing costs	15	—	—
Deferred rent	91	(33)	(20)
Changes in operating assets and liabilities:			
Accounts receivable, net	(2,163)	(2,514)	(2,340)
Inventory	(1,848)	(413)	(938)
Prepaid expenses and other current assets	(755)	(108)	(164)
Accounts payable and accrued liabilities	1,518	4,226	2,037
Other assets	(127)	36	(35)
Net cash used in operating activities	(2,188)	(7,107)	(13,305)
Investing activities			
Purchases of property and equipment	(877)	(868)	(852)
Purchase of *iDOSE* product line and related assets from DOSE Medical	(15,000)	—	—
Purchases of short-term investments	(69,751)	—	(10,817)
Proceeds from sales and maturities of short-term investments	—	—	10,711
Net cash used in investing activities	(85,628)	(868)	(958)
Financing activities			
Proceeds from public offering, net of issuance costs	113,589	—	—
Proceeds from senior secured term and draw-to term loans	6,852	—	—
Payments of senior secured term and draw-to term loans	(7,000)	—	—
Proceeds from line of credit	1,750	2,850	—
Payments of line of credit	(3,600)	(1,000)	—
Payments of subordinated notes	(7,804)	—	—
Proceeds from exercise of stock options	1,734	775	162
Proceeds from issuance of Series F preferred stock	—	—	19,227
Share purchases under Employee Stock Purchase Plan	1,161	—	—
Proceeds from exercise of stock warrants	428	875	—
Payment to acquire treasury stock	—	—	(132)
Net cash provided by financing activities	107,110	3,500	19,257
Effect of exchange rate changes on cash and cash equivalents	(26)	51	2
Net increase (decrease) in cash and cash equivalents	19,268	(4,424)	4,996
Cash and cash equivalents at beginning of period	2,304	6,728	1,732
Cash and cash equivalents at end of period	$ 21,572	$ 2,304	$ 6,728
Supplemental disclosures of cash flow information			
Interest paid	$ 834	$ 876	$ 75
Taxes paid	$ 25	$ 12	$ 4
Supplemental schedule of noncash investing and financing activities			
Purchase of intangible asset in exchange for issuance of subordinated note	$ —	$ —	$ 17,500
Purchase of intangible assets in exchange for future payments	$ 243	$ —	$ —
Conversion of convertible notes and accrued interest into Series F convertible preferred stock	$ —	$ —	$ 10,773
Conversion of preferred stock into common stock	$ 159,077	$ —	$ —
Reduction of liability upon vesting of stock options previously exercised for unvested stock	$ 86	$ 80	$ 11

Glaukos Corporation
Notes to consolidated financial statements

1. Organization and basis of presentation

Organization and business

Glaukos Corporation (Glaukos or the Company), incorporated in Delaware on July 14, 1998, is a developer, manufacturer and marketer of medical devices for the treatment of glaucoma. The accompanying consolidated financial statements include the accounts of Glaukos, its wholly ‑owned subsidiaries Glaukos Australia Pty. Ltd., Glaukos Canada Inc., Glaukos Europe GmbH, Glaukos Japan GK and through June 30, 2015, affiliated entity DOSE Medical Corporation (DOSE) (see Note 12). All significant intercompany balances and transactions among the consolidated entities have been eliminated in consolidation.

Liquidity

Since inception, the Company has not been profitable and has incurred operating losses in each year, and management expects operating losses and negative cash flows to continue for the foreseeable future. Successfully attaining profitable operations is dependent upon achieving a level of revenues adequate to support the Company's cost structure. For the year ended December 31, 2015, the Company incurred a net loss of $38.3 million and used $2.2 million of cash in operations. At December 31, 2015, the Company had an accumulated deficit of $196.6 million and does not expect to experience positive cash flows in the near future. The Company has financed operations to date primarily through private placements of equity securities, the issuance of common stock in the initial public offering (IPO) completed in June 2015, debt financings and cash generated by its commercial operations. The Company may never become profitable, and if it does, it may not be able to sustain profitability on a recurring basis. The Company plans to fund its losses and capital funding needs using existing cash and investments, cash from operations and through future debt and equity financings. There can be no assurance that the Company will be able to obtain additional financing on terms acceptable to it, or at all. Any equity financing may result in dilution to existing stockholders and any additional debt financing may include restrictive covenants. As of December 31, 2015, the Company had cash, cash equivalents and short-term investments totaling $91.1 million and net working capital of $83.8 million.

Initial public offering

On June 30, 2015, the Company completed its IPO, selling 6.9 million newly issued shares of common stock at a price of $18.00 per share. The IPO generated net cash proceeds of approximately $113.6 million, after deducting underwriting discounts and commissions of approximately $8.7 million and other related expenses of approximately $1.9 million. The underwriting discounts and commissions and offering costs were recorded as a reduction to the IPO proceeds included in additional paid ‑in capital.

Immediately prior to the closing of the IPO, all unexercised warrants to purchase shares of Series D convertible preferred stock were net exercised at the IPO price per share, and then all outstanding shares of convertible preferred stock automatically converted into approximately 21.7 million shares of common stock. Following the completion of the IPO, there were no shares of preferred stock and no warrants to purchase shares of Series D convertible preferred stock outstanding. An additional 4.5 million shares of common stock were reserved for issuance under the Company's 2015 Omnibus Incentive Compensation Plan and 450,000 shares of common stock were reserved for the Company's 2015 Employee Stock Purchase Plan.

Acquisition of certain DOSE Medical Corporation assets

On June 30, 2015, the Company acquired certain assets from DOSE, including the *iDose* product line, in exchange for a cash payment of $15.0 million and the elimination of all amounts owed by DOSE to the Company. In addition to an asset purchase, the parties agreed to an amended and restated patent license agreement and an amended and restated transition

services agreement that provides for limited support from the Company to DOSE for a period of up to three years (see Note 1 2).

Reverse stock split

On June 11, 2015, the Company effected a 1 for 2.5 share reverse stock split of the Company's common stock and convertible preferred stock. Neither the par value nor the authorized number of shares was adjusted as a result of the reverse stock split. All issued and outstanding common stock, shares of common stock held in treasury, convertible preferred stock, warrants, and per share amounts contained in the accompanying financial statements and notes to the financial statements have been retroactively adjusted to give effect to the reverse stock split for all periods presente d.

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 financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. Actual results could differ materially from those estimates and assumptions . Management considers many factors in selecting appropriate financial accounting policies and controls and in developing the estimates and assumptions that are used in the preparation of these financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes, and management must select an amount that falls within that range of reasonable estimates. The most significant estimates in the accompanying consolidated financial statements relate to revenue recognition, inventory reserves and stock -based compensation expense. Although these estimates are based on the Company's knowledge of current events and actions it may undertake in the future, this process may result in actual results differing materially from those estimated amounts used in the preparation of the financial statements.

Foreign currency translation

The accompanying consolidated financial statements are presented in U.S. dollars. The Company considers the local currency to be the functional currency for its international subsidiaries. Accordingly, their assets and liabilities are translated into U.S. dollars using the exchange rate in effect on the balance sheet date. Revenues and expenses are translated at average exchange rates prevailing throughout the periods presented. Currency translation adjustments arising from period to period are charged or credited to accumulated other comprehensive income (loss) in stockholders ' equity (deficit). For the years ended December 31, 2015, 2014 and 2013, the Company reported income from foreign currency translation adjustments of approximately $ 155, 000, $42,000 and $2,000, respectively. Realized gains and losses resulting from foreign currency transactions are included in selling, general and administrative expense in the consolidated statements of operations. For the years ended December 31, 2015, 2014 and 2013, the Company reported foreign currency transaction losses of approximately $ 287, 000 , $38,000 and $10,000 , respectively.

Cash , cash equivalents and short-term investments

The Company invests its excess cash in marketable securities, including money market funds, money market securities, corporate bonds, and corporate commercial paper and U.S. government agency bonds. 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. From time to time, the Company maintains cash balances in excess of amounts insured by the Federal Deposit Insurance

Commission (FDIC). 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 income within stockholders' equity (deficit).

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, 2015, 2014 and 2013.

Realized gains and losses and declines in value, if any, judged to be other ‑than ‑temporary on available ‑for ‑sale securities, are reported in interest income or 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. Accrued interest and dividends are included in interest income. 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.

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 2015 , 2014 and 2013 , none of the Company's customers accounted for more than 10% of revenues.

Restricted cash

The Company has a credit card facility with its primary operating bank which is collateralized by certificates of deposit maintained at the bank.

Accounts receivable

The Company sells its products directly to hospitals, surgery centers and distributors in the U.S. and internationally. The Company periodically assesses the payment performance of these customers and establishes reserves for anticipated losses when necessary, which losses historically have not been significant and have not exceeded management's estimates. Accounts receivable are recorded at the invoiced amount and do not bear interest. The Company maintains an allowance for doubtful accounts based on historical collection experience and expectations of future collection based on current market conditions. The allowance for doubtful accounts is management's best estimate of the amount of probable credit losses. Account balances are charged against the allowance when it is probable the receivable will not be recovered. The Company's allowance for bad debts was $ 83, 000 and $50,000 as of December 31, 2015 and 2014, respectively, and no customers accounted for more than 10% of net accounts receivable as of either date .

The Company generally permits returns of product from customers if such product is returned in a timely manner and in good condition. Estimated allowances for sales returns are based upon the Company's historical patterns of product returns matched against sales, and management's evaluation of specific factors that may increase the risk of product returns.

Inventory

Inventory is valued at the lower of cost or market (net realizable value). Cost is determined by the first -in, first -out method. Management evaluates inventory for excess quantities and obsolescence and records an allowance to reduce the carrying value of inventory as determined necessary.

Long lived assets

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 dictate, based upon undiscounted future operating cash flows, 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.

Intangible assets

Intangible assets are recorded at cost and are amortized over the estimated useful life. I ntangible asset s in the accompanying balance sheet is currently comprised of the cost of the Company's buyout of a royalty payment obligation and the value of non-compete agreements entered into in 2015 with two former international distributors . See Note 6.

Fair value measurements

Assets and liabilities are measured using quoted prices in active markets and total fair value is the published market price per unit multiplied by the number of units held without consideration of transaction costs. Assets and liabilities that are measured using significant other observable inputs are valued by reference to similar assets or liabilities, adjusted for contract restrictions and other terms specific to that asset or liability. For these items, a significant portion of fair value is derived by reference to quoted prices of similar assets or liabilities in active markets. For all remaining assets and liabilities, fair value is derived using a fair value model, such as a discounted cash flow model or Black -Scholes model.

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. Based on the borrowing rates currently available to the Company for loans with similar terms, the Company believes that the fair value of long -term debt approximates its carrying value. The carrying amount of the warrant liability and non -controlling interest represent their fair values.

The valuation of assets and liabilities are 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).

Revenue recognition

The Company recognizes revenue from product sales when the following criteria are met: goods are shipped, title and risk of loss has transferred to its customers, persuasive evidence of an arrangement exists and collectability is reasonably assured. Persuasive evidence of an arrangement exists when there is a contractual arrangement in place with the customer. Delivery has occurred when a product is shipped. If persuasive evidence of an arrangement exists and delivery has occurred, the Company determines whether the invoiced amount is fixed or determinable and collectability of the invoiced amount is reasonably assured. The Company assesses whether the invoiced amount is fixed or determinable based on the existing arrangement with the customer, including whether the Company has sufficient history with a customer to reliably estimate the customer's payment patterns. The Company assesses collectability by evaluating historical cash receipts and individual customer outstanding balances. To the extent all criteria set forth above are not satisfied at the time of shipment, revenue is recognized when cash is received from the customer.

Customers are not granted specific rights of return; however, the Company may permit returns of product from customers if such product is returned in a timely manner and in good condition. The Company provides a warranty on its products for one year from the date of shipment, and any product found to be defective or out of specification will be replaced 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.

Shipping and handling costs

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

Advertising costs

All advertising costs are expensed as incurred. Advertising costs incurred during the years ended December 31, 2015, 2014 and 2013 were approximately $0. 8 million, $0.4 million and $0.5 million, respectively.

Stock warrants

The Company has issued freestanding warrants to purchase shares of its convertible preferred stock which are accounted for as a liability due to the nature of the underlying redemption provisions of the preferred stock into which the warrants are exercisable. The Company has also issued freestanding warrants to purchase shares of its common stock which are accounted for as a liability because they contain a down -round protection provision that is outside the control of the Company. The warrants are recorded on the Company's balance sheet at their fair value as determined on the date of issuance and are revalued at each subsequent balance sheet date, with fair value changes recognized as other income or expense in the accompanying consolidated statements of operations. The Company will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrants. The Company estimates the fair value of the liability using option pricing models and assumptions that are based on the individual characteristics of the warrants or instruments on the valuation date, including assumptions for expected volatility, expected life, yield, and risk -free interest rate.

Income taxes

The Company recognizes deferred tax assets and liabilities for temporary differences between the financial reporting basis and the tax basis of the Company's assets and liabilities, along with net operating loss and tax credit carryovers. The Company records a valuation allowance against its 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 evidence, which includes the Company's historical operating performance and limited potential to utilize tax credit carryforwards, the Company has determined that total deferred tax assets should be fully offset by a valuation

allowance. When the Company establishes or reduces the valuation allowance against its deferred tax assets, its provision for income taxes will increase or decrease, 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 preparation of these state 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 by us.

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 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 costs of clinical study activities performed 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, 2015.

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. The fair value of stock ‑based awards made to employees is estimated at the grant date using the Black ‑Scholes option ‑pricing model, and the portion that is ultimately expected to vest is recognized as compensation cost over the requisite service period using the straight ‑line method. The determination of the fair value ‑based measurement of stock options on the date of grant using an option pricing model is affected by the determination of the fair value of the underlying stock as well as assumptions regarding a number of highly complex and subjective variables. These variables include, but are not limited to, the Company's stock price volatility over the expected term of the grants, and actual and projected employee stock option exercise behaviors. In the future, as additional empirical evidence regarding these estimates becomes available, the Company may change or refine its approach of deriving them, and these changes could impact the fair value ‑based measurement of stock options granted in the future. Changes in the fair value ‑based measurement of stock awards could materially impact the Company's operating results. The fair values of stock ‑based awards made to nonemployees are remeasured at each reporting period using the Black ‑Scholes option ‑pricing model. Compensation expense for these stock ‑based awards is determined by applying the remeasured fair values to the shares that have vested during a period.

Comprehensive loss

All components of comprehensive loss, including net loss, are reported in the 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 common stock equivalents. Diluted net loss per share is calculated by dividing the net loss by the sum of the weighted -average number of dilutive common share equivalents outstanding for the period determined using the treasury -stock method. Common stock equivalents are comprised of convertible preferred stock, stock warrants, and stock options outstanding under the Company's stock option plans. The calculation of diluted net loss per share requires that, to the extent the average fair value of the underlying shares for the reporting period exceeds the exercise price of the warrants and the presumed exercise of such securities are dilutive to net loss per share for the period, adjustments to net loss used in the calculation are required to remove the change in fair value of the warrants for the period. Likewise, adjustments to the denominator are required to reflect the related dilutive shares. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position and stock warrants being anti -dilutive.

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

	As of December 31,		
	2015	2014	2013
Convertible preferred stock outstanding	—	21,642	21,508
Preferred stock warrants outstanding	—	128	343
Common stock warrants outstanding	6	—	—
Stock options outstanding	5,701	5,657	4,472
Employee stock purchase plan	89	—	—
	5,796	27,427	26,323

Recent accounting pronouncements

In April 2014, the Financial Accounting Standards Board (FASB) issued an accounting standards update (ASU) that raises the threshold for disposals to qualify as discontinued operations and allows companies to have significant continuing involvement with and continuing cash flows from or to the discontinued operation. It also requires additional disclosures for discontinued operations and new disclosures for individually material disposal transactions that do not meet the definition of a discontinued operation. This guidance was effective for fiscal years beginning after December 15, 2014, which was the Company's fiscal year 2015, with early adoption permitted. A doption of the guidance did not have a material impact on the Company's consolidated financial statements.

In May 2014, the FASB issued guidance codified in Accounting Standard Codification (ASC) 606, *Revenue Recognition—Revenue from Contracts with Customers* , which amends the guidance in former ASC 605, *Revenue Recognition* , which provides a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and will supersede most current revenue recognition guidance. This ASU is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. In July 2015, the FASB deferred the effective date for annual reporting periods beginning after December 15, 2017 (including interim periods within those periods). Early adoption is permitted to the original effective date of December 15, 2016 (including interim periods within those periods). The Company is currently evaluating the impact of the provisions of ASC 606 on its consolidated financial statements.

In June 2014, the FASB issued an ASU that requires a performance target that affects vesting of a share -based payment award and that could be achieved after the requisite service period to be treated as a performance condition. As such, the performance target should not be reflected in estimating the grant date fair value of the award. Compensation cost should

be recognized over the required service period if it is probable that the performance target will be achieved. This guidance will be effective for fiscal years beginning after December 15, 2015, which will be the Company's fiscal year 2016, with early adoption permitted. The Company does not expect the adoption of the guidance to have material impact on the Company's consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014 -15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* . This ASU introduces an explicit requirement for management to assess if there is substantial doubt about an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. In connection with each annual and interim period, management must assess if there is substantial doubt about an entity's ability to continue as a going concern within one year after the issuance date. Disclosures are required if conditions give rise to substantial doubt. ASU 2014 -15 is effective for all entities in the first annual period ending after December 15, 2016. The Company is currently assessing the potential effects of this ASU on the consolidated financial statements.

In February 2015, the FASB issued Accounting Standards Update (ASU) 2015 -02, *Amendments to the Consolidation Analysis* , which eliminates the deferral of FAS 167, which allows reporting entities with interests in certain investment funds to follow the consolidation guidance in FIN 46(R), and make other changes to both the variable interest model and the voting model. The ASU is effective for annual periods beginning after December 15, 2015 and interim periods therein, with early adoption permitted. During 2015, the Company early adopted the provisions of the ASU effective January 1, 2015. Based on the asset purchase transaction with DOSE on June 30, 2015 and the Company's evaluation of the modified relationship with DOSE, management determined that after the transaction DOSE is no longer a variable interest entity (VIE) requiring consolidation (See Note 1 2).

In July 2015, the FASB issued ASU 2015 -11, Inventory (Topic 330), *Simplifying the Measurement of Inventory* , which changes the measurement principle for inventory from the lower of cost or market to the lower of cost and net realizable value. ASU 2015 -11 defines net realizable value as estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The new guidance must be applied on a prospective basis and is effective for fiscal years beginning after December 15, 2015, and interim periods within those years, with early adoption permitted. The Company does not believe the implementation of this standard will have a material impact on its consolidated financial statements.

In November 2015, the FASB issued guidance on balance sheet classification of deferred taxes. Current GAAP requires an entity to separate deferred income tax liabilities and assets into current and noncurrent amounts in a classified statement of financial position. To simplify the presentation of deferred income taxes, the new guidance requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by this new guidance. The new guidance is effective for fiscal years beginning after December 15, 2016, and interim periods within those annual periods. Earlier application is permitted for all entities as of the beginning of an interim or annual reporting period. For the year ended December 31, 2015, the Company has elected to early adopt this update and will present all its deferred tax assets and liabilities as non-current for the period ended December 31, 2015. The Company has applied the Standard on a prospective basis. Therefore, the classifications of deferred tax assets and liabilities in periods prior to the period ended December 31, 2015 have not been changed from the original presentation.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The ASU requires management to recognize lease assets and lease liabilities by lessees for all operating leases. The ASU is effective for periods ending on December 15, 2018 and interim periods therein on a modified retrospective basis. The Company is currently evaluating the impact this guidance will have on its consolidated financial statements.

3. Balance sheet details

Short-term investments

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

		At December 31, 2015			
	Maturity (in years)	Amortized cost or cost	Unrealized gains	Unrealized losses	Estimated fair value
Government agency bonds	1 - 3	$ 5,513	$	$ 10	$ 5,503
Commercial paper	less than 1	12,342	—	2	12,340
Corporate notes	1-3	45,051	—	110	44,941
Asset-backed securities	1-3	6,794	—	26	6,768
Total		$ 69,700	$ —	$ 148	$ 69,552

The Company had no short-term investments at December 31, 2014.

Accounts receivable, net

Accounts receivable consisted of the following (in thousands):

	December 31,	
	2015	2014
Accounts receivable	$ 7,632	$ 5,448
Less allowance for doubtful accounts	(83)	(50)
Total	$ 7,549	$ 5,398

Inventory

Inventory consisted of the following (in thousands):

	December 31,	
	2015	2014
Finished goods	$ 953	$ 962
Work in process	503	194
Raw material	2,641	1,102
	$ 4,097	$ 2,258

Property and equipment, net

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

	December 31,	
	2015	2014
Equipment	$ 4,597	$ 4,038
Furniture and fixtures	387	376
Leasehold improvements	1,011	985
Computer equipment and software	836	762
	6,831	6,161
Less accumulated depreciation and amortization	(4,677)	(4,211)
	$ 2,154	$ 1,950

Depreciation and amortization expense related to property and equipment was $0.8 million, $0.7 million and $ 0 . 6 million for the years ended December 31, 2015, 2014 and 2013, respectively.

Accrued liabilities

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2015	2014
Accrued contract payments (see Note 11)	$ 504	$ 2,604
Accrued bonuses	3,721	1,695
Accrued vacation benefits	1,007	746
Other accrued liabilities	2,561	1,417
	$ 7,793	$ 6,462

4. Fair value measurements

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 following ta bles present information about the Company's financial assets and financial liabilities measured at fair value on a recurring basis as of December 31, 2015 and 2014, and indicates the fair value hierarchy of the valuation techniques utilized by the Company to determine such fair value (in thousands):

	At December 31, 2015			
	December 31, 2015	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets				
Money market funds [(i)]	$ 13,922	$ 13,922	$ —	$ —
Government agency bonds [(ii)]	5,523	—	5,523	—
Commercial paper [(ii)]	15,340	—	15,340	—
Corporate notes [(ii)]	45,159	—	45,159	—
Asset-backed securities [(ii)]	6,775	—	6,775	—
Total assets	$ 86,719	$ 13,922	$ 72,797	$ —
Liabilities				
Stock warrant liability	$ 105	$ —	$ —	$ 105
Total liabilities	$ 105	$ —	$ —	$ 105

(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 cash and cash equivalents or short-term investments on the consolidated balance sheets.

	At December 31, 2014			
	December 31, 2014	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets				
Cash equivalents	$ —	$ —	$ —	$ —
Total assets	$ —	$ —	$ —	$ —
Liabilities				
Stock warrant liability	$ 379	$ —	$ —	$ 379
Total liabilities	$ 379	$ —	$ —	$ 379

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, commercial paper, 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. 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.

The stock warrant liabilit y is recorded at fair value using the Black Scholes option pricing model, which requires inputs such as the expected term of the warrant, volatility and risk free interest rate. These inputs are subjective and generally require significant analysis and judgment to develop, and are therefore considered Level 3 inputs.

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

In con junction with the Company's February 2015 Amended and Restated Revolving Credit and Term Loan Agreement as more fully described in Note 6, the Company issued warrants to the lenders to purchase 11,298 shares of common stock at an exercise price of $8.85 per share. Warrants to purchase 5,649 shares of common stock were exercised by the lenders in September 2015. For the year ended December 31, 2015, the Company recorded other expense of $0.2 million related to changes in the fair value of the warrants. The fair value of the warrants as of the issuance date was estimated to be $53,000 using an option pricing framework considering multiple exit scenarios and the probability of a down -round financing. The following assumptions were deemed by the Company to be significant unobservable inputs: risk -free interest rate of 1.9%; dividend yield of 0.0%; expected volatility of 70.0%; and an expected life of 7 years. The fair value of the warrants to purchase the remaining 5,649 shares of common stock as of December 31, 2015 was estimated to be $0.1 million using the Black -Scholes valuation model with the following assumptions deemed by the Company to be significant unobservable inputs: risk -free interest rate of 1.9%; dividend yield of 0.0%; expected volatility of 54.8%; and an expected life of 6.2 years. If the value of the underlying shares were to decrease by 10%, the fair value of the warrants would decrease by approximately the same amount.

In conjunction with loans to the Company in 2010 from certain holders of the Company's then -outstanding preferred stock, which shares were subsequently converted into preferred stock in 2011, the Company issued warrants to such holders to purchase 156,860 shares of Series D convertible preferred stock at $7.65 per share. Warrants to purchase 29,334 shares were exercised in 2014. Warrants to purchase 127,526 shares were exercised in 2015; 49,410 warrant shares were exercised with cash payment and 78,116 warrant shares were net exercised into 44,914 shares of common stock immediately prior to the IPO at the IPO price per share of $18.00 per share. For the years ended December 31, 2015, 2014 and 2013, the Company recorded other income of approximately $0.9 million, $5,000 and $0.3 million, respectively, related to changes in the fair value of the warrants.

In conjunction with loans in 2006 from certain holders of the Company's preferred stock, which were repaid in 2007, the Company issued warrants to purchase 185,714 shares of Series C preferred stock at $7.00 per share. All of these warrants were exercised in January 2014. For the years ended December 31, 2015, 2014 and 2013, the Company recorded other income of $0 , $0 and $0.1 million, respectively , related to changes in the fair value of the warrants .

The following table provides a reconciliation of liabilities measured at fair value using level 3 significant unobservable inputs (Level 3) on a recurring basis (in thousands):

		Warrant liability
Balance at December 31, 2013	$	680
Issuance of Series C convertible preferred stock in connection with exercises of preferred stock warrants		(186)
Issuance of Series D convertible preferred stock in connection with exercises of preferred stock warrants		(110)
Change in the fair value of stock warrants		(5)
Balance at December 31, 2014		379
Issuance of common stock warrants		53
Change in the fair value of stock warrants		1,132
Issuance of Series D convertible preferred stock in connection with exercises of preferred stock warrants		(1,320)
Issuance of common stock in connection with exercise of common stock warrant		(139)
Balance at December 31, 2015	$	105

5. Convertible notes payable

In August and October 2012, the Company entered into convertible note agreements with certain holders of its preferred stock to borrow an aggregate of $10.5 million. The convertible notes included the following terms and conditions: (1) interest rate of 7.0%; (2) principal and interest due upon the earlier of a change in control event or demand at any time after January 31, 2013; and (3) automatic conversion of principal and accrued interest into shares of preferred stock at a conversion price equal to the purchase price per share of the equity security issued and sold in the next preferred stock financing. Amounts borrowed under the convertible notes were unsecured. In January 2013, the principal amount

of the convertible notes and all accrued interest were converted into shares of Series F convertible preferred stock pursuant to the terms of the convertible note agreements.

6. Long -term debt

Notes payable in connection with GMP Vision Solutions

In January 2007, the Company entered into an agreement (the Original GMP Agreement) with GMP Vision Solutions, Inc. (GMP) to acquire certain in -process research and development. In connection with the Original GMP Agreement, the Company was obligated to make periodic royalty payments equal to a single -digit percentage of revenues received for royalty -bearing products and periodic royalty payments at a higher royalty rate applied to all amounts received in connection with the grant of licenses or sublicenses of the related intellectual property. No related royalty expense was recorded in cost of sales in the years ended December 31, 2015, 2014 and 2013.

In December 2012, the Company entered into an agreement with GMP in which it paid GMP $1.0 million for a 90 -day option to buy out all remaining royalties payable to GMP. In April 2013, the option expired unexercised, and as provided in the agreement, the $1.0 million payment satisfied the Company's obligation to pay the first $1.0 million in royalties earned beginning on January 1, 2013. The $1.0 million payment was recorded in cost of sales in the year ended December 31, 2012.

In November 2013, the Company entered into an amended agreement with GMP in which remaining royalties payable to GMP (the Buyout Agreement) were canceled in exchange for the issuance of $17.5 million in promissory notes payable to GMP and a party related to GMP (together, the GMP Note Parties). The GMP notes are collateralized by all of the Company's assets, excluding intellectual property. However, in connection with the Buyout Agreement, the GMP Note Parties entered into agreements with the Company's primary bank pursuant to which any collateralized interests, liens, rights of payment or ability to initiate any enforcement actions in the event of an event of default were subordinate to the rights of the Company's primary bank under the Credit Agreement (and subsequently, the Amended Credit Agreement) which was paid off in full on July 31, 2015 (see Note 6).

The Buyout Agreement also calls for a payment of up to $2.0 million in the event of a sale of the Company meeting certain criteria. The promissory notes carry an interest rate of 5% per annum and required monthly interest only payments from November 30, 2013 through December 31, 2014 of $72,900 , followed by 24 equal monthly principal and interest payments of $767,700 , which began on January 31, 2015, and end on December 31, 2016.

The Company concluded that the $17.5 million transaction represented the purchase of an intangible asset. The Company estimated a useful life of five years over which the intangible asset will be amortized to cost of sales in the accompanying statements of operations, which amortization period was determined after consideration of the projected outgoing royalty payment stream had the Buyout Agreement not occurred, and the remaining life of the patents obtained in the Original GMP Agreement. After determining that the pattern of future cash flows assoc iated with this intangible asset could not be reliably estimated with a high level of precision, the Company concluded that the intangible asset will be amortized on a straight -line basis over the estimated useful life.

Bank loan facility

In June 2013, the Company entered into a Loan and Security Agreement (the Credit Agreement) with the Company's primary bank, under which the bank agreed to extend to the Company a line of credit in the maximum principal amount of $6.0 million. Advances under the line of credit were limited to the lesser of (i) $6.0 million or (ii) 77% of the sum of cash, cash equivalents and eligible domestic accounts receivable. The entire unpaid principal amount plus any accrued but unpaid interest were to become due and payable in full on June 5, 2015. Obligations under the Credit Agreement bore interest on the outstanding daily balance thereof at the bank's prime rate plus 0.5% (3.75% at December 31, 2014). Amounts owed were secured by a first priority security interest in all of the Company's assets, excluding intellectual property. The Credit Agreement included certain reporting and financial covenants which, if not met, could have constituted an event of default under the Credit Agreement. As of December 31, 2015 and 2014, the balance outstanding on the line of credit was $0 and $1.9 million, respectively. In February 2015, the Agreement was amended and restated, at which time the balance outstanding on the line of credit was $2.1 million.

In February 2015, the Company and its primary bank executed an Amended and Restated Revolving Credit and Term Loan Agreement (the Amended Credit Agreement) which provided for a $5.0 million senior secured term loan, a $5.0 million senior secured draw -to term loan and an $8.0 million senior secured revolving credit facility. Amounts owed under the Amended Credit Agreement were secured by a first priority security interest in all of the Company's assets, excluding intellectual property. The Amended Credit Agreement included certain reporting and financial covenants which, if not met, could have constituted an event of default under the Amended Credit Agreement.

On the closing date, the Company received $5.0 million cash under the senior secured term loan and immediately paid off the $2.1 million balance outstanding on the line of credit under the Credit Agreement. The Company incurred loan origination fees of $41,000 which was recorded as a loan discount, and debt issuance costs of $0.1 million which was recorded as a deferred asset. The term loan required quarterly principal payments of $0.4 million over a three -year period beginning May 1, 2016. The senior secured draw -to term loan was available through February 23, 2016 for advances up to an aggregate of $5.0 million, and it required quarterly principal payments equal to 1/12 of the aggregate principal amount over a three -year period beginning May 1, 2016. As of July 31, 2015, the Company had drawn $2.0 million under the draw -to term loan. The senior secured term loan and draw -to term loan would have matured and would have been required to be fully paid by February 23, 2019. Advances under the revolving line of credit were limited to the lesser of (i) $8.0 million or (ii) a calculated borrowing base consisting of (a) 80% of eligible accounts receivable plus (b) the lesser of 30% of eligible inventory or $1.5 million. The entire unpaid principal amount plus any accrued but unpaid interest under the revolving line of credit were due to become payable in full on February 23, 2017. The Company was permitted to make voluntary prepayments of the term and draw -to term loans without prepayment penalty. On July 31, 2015, the Company paid off in full all amounts outstanding under the Amended Credit Agreement with the payment of $7.0 million in principal plus all interest and fees payable through the payoff date, and recorded a loss on extinguishment of debt in the amount of $0.2 million. Accordingly, this facility was terminated and is no longer outstanding and available to the Company.

Outstanding balances under the senior secured term loan and senior secured draw -to term loan bore interest on the outstanding daily balance at an annual percentage rate equal to the bank's prime rate plus 2% . At the Company's option all or a portion of the amounts owed under any of the senior secured term loan and draw -to term loan may have been converted into Eurodollar -based advances at an annual percentage rate equal to LIBOR plus 3% . Outstanding balances under the revolving credit facility bore interest on the outstanding daily balance thereof at an annual percentage rate equal to the bank's prime rate plus 1.75% . At the Company's option all or a portion of the amounts owed under the revolving credit facility may have been converted into Eurodollar -based advances at an annual percentage rate equal to LIBOR plus 2.75% .

In connection with the execution of the Amended Credit Agreement, the Company issued warrants to the lenders to purchase an aggregate of 11,298 shares of common stock at an exercise price of $8.85 per share as more fully described in Note 4. Warrants to purchase 5,649 shares of common stock were exercised by the lenders in September 2015.

The Company accounted for the debt discount and deferred asset utilizing the effective interest method. Amortization of debt discount and the deferred asset to interest expense amounted to $15,000 for the year ended December 31, 2015.

The Company's debt balances, including current portions, were as follows (in thousands):

	December 31,	
	2015	2014
Notes payable	$ 9,696	$ 17,500
Total debt	9,696	17,500
Less current portion of long-term debt	(8,931)	(8,532)
Total long-term debt	$ 765	$ 8,968

In 2015, the Company entered into agreements with two international distributors pursuant to which their distribution rights with the Company were terminated effective as of December 31, 2015. As part of the agreements the distributors agreed to provide certain services to, and not compete with, the Company for one-to-two years in exchange for payments calculated based on single-digit percentages of the Company's future revenues in those years in the countries that had

comprised their territories. Management recorded the estimated fair value of the non-compete provisions as an intangible asset of approximately $0.3 million, which will be amortized on a straight-line basis to selling, general and administrative expense over the one -to- two year period .

The following reflects the composition of intangible assets, net (in thousands):

	December 31, 2015	December 31, 2014
GMP royalty buyout	$ 17,500	$ 17,500
Non-compete agreements	243	—
	17,743	17,500
Accumulated amortization	(7,525)	(4,025)
Total	$ 10,218	$ 13,475
Weighted average amortization period (in months)	60	60

In the years ended December 31, 2015, 2014 and 2013, the Company recorded related amortization expense of $3.5 million, $3.5 million and $0.5 million in cost of sales. Estimated amortization expense will be $3.7 million in 2016, $3.6 million in 2017 and $3.0 million in 2018 .

7. Convertible preferred stock

Immediately prior to the completion of the IPO, and after all unexercised warrants to purchase shares of Series D convertible preferred stock were net exercised at the IPO price per share, the Company had outstanding 21,736,367 shares of convertible preferred stock which automatically converted into 21,736,367 shares of the Company's common stock. The related carrying value of $159.1 million was reclassified to additional paid-in capital in the period ending June 30, 2015, and no shares of convertible preferred stock were outstanding thereafter .

The following reflects the composition of convertible preferred stock as of December 31, 2014 (in thousands, except per share amounts):

Series A convertible preferred stock, $0.001 par value; 3,000 shares authorized and 1,200 shares issued and outstanding at December 31, 2014; liquidation preference of $3,000 at December 31, 2014	$ 3,000
Series B convertible preferred stock, $0.001 par value; 5,805 shares authorized and 2,322 shares issued and outstanding at December 31, 2014; liquidation preference of $12,538 at December 31, 2014	12,547
Series C convertible preferred stock, $0.001 par value; 14,750 shares authorized and 5,819 shares issued and outstanding at December 31, 2014 ; liquidation preference of $40,731 at December 31, 2014	40,836
Series D convertible preferred stock, $0.001 par value; 13,844 shares authorized and 5,410 shares issued and outstanding at December 31, 2014; liquidation preference of $41,387 at December 31, 2014	41,496
Series E convertible preferred stock, $0.001 par value; 8,754 shares authorized and 3,501 shares issued and outstanding at December 31, 2014; liquidation preference of $29,500 at December 31, 2014	29,500
Series F convertible preferred stock, $0.001 par value; 8,474 shares authorized and 3,390 shares issued and outstanding at December 31, 2014; liquidation preference of $30,000 at December 31, 2014	30,000
Total	$ 157,379

8. Stockholders' equity

Convertible preferred stock

On June 30, 2015, in connection with the closing of the Company's IPO, all shares of convertible preferred stock automatically converted into common stock at a conversion ratio of one -to -one.

Until the conversion of the Company's convertible preferred stock into common stock in conjunction with the IPO, it was classified as temporary equity in the accompanying consolidated balance sheets in accordance with authoritative guidance. The preferred stock was not redeemable; however, upon certain change in control events that are outside of the Company's control, including liquidation, sale or transfer of control of the Company, holders of the convertible preferred stock had the right to receive their liquidation preference under the terms of the Company's pre -IPO certificate of incorporation. Accordingly, the Company did not recognize any accretion of the value of the convertible preferred stock.

In January 2013, the Company issued 3.4 million shares of Series F convertible preferred stock (Series F) for $30.0 million, or $8.85 per share. Cash of $19.2 million was paid for 2.2 million Series F shares and a total of $10.8 million in principal and accrued interest due under convertible notes was converted into 1.2 million Series F shares.

The relative rights, terms, privileges, and restrictions that were granted to or imposed upon preferred stockholders are described below:

Dividends

The holders of Series A, B, C, D, E and F convertible preferred stock were entitled to receive annual noncumulative dividends of $0.20 , $0.432 , $0.56 , $0.612 , $0.674 and $0.708 per share, respectively, when and if declared by the Board of Directors, prior and in preference to shareholders of common stock. N o dividends were ever declared on the convertible preferred stock .

Liquidation preference

In the event of a liquidation of the Company, holders of Series A, B, C, D, E and F preferred stock were entitled to a liquidation preference of $2.50 , $5.40 , $7.00 , $7.65 , $8.43 and $8.85 per share, as adjusted for any stock dividends, combinations, or splits with respect to such shares, respectively, and any declared but unpaid dividends prior and in preference to any distribution of the assets of the corporation. The remaining assets of the Company were to have been distributed on a pro rata basis to the holders of the common stock.

Conversion rights

Each share of Series A, B, C, D, E and F preferred stock was convertible at the option of the holder, at any time after the date of issuance, into common stock at the initial conversion rate of one -to -one. The conversion rate was subject to adjustment for antidilution provisions as defined. The Series A, B, C, D, E and F preferred stock was automatically convertible into common shares upon the earlier of: (a) the day immediately preceding the closing of an underwritten public offering in which the Company receives $50.0 million or more in gross proceeds or (b) the receipt of consent of the holders of at least 67% of the then outstanding shares of preferred stock, voting together as a single class. On June 30, 2015, in connection with the closing of the Company's IPO, all shares of convertible preferred stock automatically converted into common stock at the conversion ratio of one -to -one.

Voting rights

Each share of Series A, B, C, D, E and F preferred stock had voting rights equal to an equivalent number of shares of common stock into which it was convertible. The preferred stockholders were entitled to vote as a separate class under specific circumstances.

As long as at least 1.4 million shares of preferred stock remained outstanding, the Company was required to obtain approval from at least 67% of the holders of preferred stock in order to, among other things, alter the certificate of incorporation as related to preferred stock, change the authorized number of shares of preferred stock, acquire a business, or effect a merger, consolidation or sale of assets where the existing stockholders retain less than 51% of the voting stock of the surviving entity.

In addition to any other vote required by law or the Company's certificate of incorporation, (a) as long as 0.4 million shares of Series E preferred stock were outstanding, the Company was required to obtain the approval of the holders of a majority of the Series E preferred stock in order to, among other things, alter the certificate of incorporation as it relates to the Series E preferred stock, change the authorized number of shares of Series E preferred stock, sell or license the Company's assets or effect a merger or consolidation where the existing stockholders retain less than 51% of the voting power of the surviving corporation and the stock price is less than $15.30 per share, or take any action that would alter or waive certain liquidation rights of the Series E preferred stock and (b) as long as 0.2 million shares of Series F preferred stock were outstanding, the Company was required to obtain the approval of the holders of at least 60% of the Series F preferred stock in order to, among other things, alter the certificate of incorporation as it relates to the Series F preferred stock, change the authorized number of shares of Series E preferred stock, sell or license the Company's assets or effect a merger or consolidation where the existing stockholders retain less than 51% of the voting power of the surviving corporation and the stock price is less than $15.30 per share, or take any action that would alter or waive certain liquidation rights of the Series F preferred stock.

Preferred stock

The Company is authorized to issue 5.0 million shares of its preferred stock. No shares of preferred stock have been issued since it was authorized in June 2015 .

Common stock

Prior to the completion of the Company's IPO in June 2015, all common stock issued resulted from the founding of the Company and the exercises of stock options. On June 30, 2015, the Company completed its IPO, selling 6.9 million newly issued shares of common stock at a price of $18.00 per share. Immediately prior to the closing of the IPO, all unexercised warrants to purchase shares of Series D convertible preferred stock were net exercised at the IPO price per share, and then all outstanding shares of convertible preferred stock automatically converted into approximately 21.7 million shares of common stock.

In 2013, the Company repurchased at fair market value and placed into treasury 28,000 shares of its common stock that had been acquired in connection with the exercise of a stock option.

Stock - based compensation

The Company has four stock -based compensation plans (collectively, the Stock Plans)—the 2001 Stock Option Plan (the 2001 Stock Plan), the 2011 Stock Plan, the 2015 Omnibus Incentive Compensation Plan (the 2015 Stock Plan) and the 2015 Employee Stock Purchase Plan (the ESPP). The purpose of these plans is to provide incentives to employees, directors and nonemployee consultants. The Company will no longer grant any awards under the 2001 Stock Plan and the 2011 Stock Plan. The maximum term of any stock options granted under the Stock Plans is 10 years. The 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. The Company reserved an aggregate of 4.5 million shares of common stock for issuance under the 2015 Stock Plan, and 450,000 shares of common stock for issuance under the ESPP that permits eligible employees to purchase shares of t he Company's common stock, using contributions via payroll deduction of up to 15% of the ir 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.

Stock options granted pursuant to the 2001 Stock Plan and 2011 Stock Plan generally permit optionees to elect to exercise unvested options in exchange for restricted common stock. All unvested shares issued upon the early exercise of stock options, so long as they remain unvested, are subject to the Company's right of repurchase at the optionee's original exercise price for a 90 -day period beginning on the date that an optionee's service with the Company voluntarily or involuntarily terminates. Consistent with authoritative guidance, early exercises are not considered exercises for accounting purposes. Cash received for the exercise of unvested options is recorded as a liability, which liability is released to equity at each reporting date as the shares vest. During the years ended December 31, 2015, 2014 and 2013, there were option exercises for 337 , 55,908 and 0 unvested shares, respectively. As of December 31, 2015 and 2014, 16,682 and 38,678 shares, respectively, remained subject to a repurchase right by the Company . As of December 31, 2015 and 2014, the related liability, which is included in other accrued liabilities in the accompanying consolidated balance sheets, was approximately $67,000 and $153,000 , respectively.

The following table summarizes stock option activity under the 2001 Stock Plan, 2011 Stock Plan and 2015 Stock Plan (in thousands):

	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, 2012	3,823	$ 2.28	6.4	
Granted	871	4.3		
Exercised	(118)	1.38		$ 359
Canceled/forfeited/expired	(104)	3.8		
Outstanding at December 31, 2013	4,472	$ 2.65	6.2	$ 9,299
Granted	1,571	7.13		
Exercised	(348)	1.98		$ 1,249
Canceled/forfeited/expired	(38)	4.85		
Outstanding at December 31, 2014	5,657	$ 3.93	6.3	$ 16,131
Granted	1,139	18.07		
Exercised	(1,022)	1.7		$ 9,174
Canceled/forfeited/expired	(73)	6.56		
Outstanding at December 31, 2015	5,701	$ 7.1	6.7	$ 102,390
Vested and expected to vest at December 31, 2015	5,635	$ 7.02		$ 101,632
Exercisable at December 31, 2015	3,782	$ 4.03		$ 78,133

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.

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 following table summarizes the allocation of stock -based compensation in the accompanying consolidated statements of operations (in thousands):

	Year ended December 31,		
	2015	2014	2013
Cost of sales	$ 251	$ 38	$ 15
Selling, general & administrative	5,773	1,118	959
Research and development	1,865	374	372
Total	$ 7,889	$ 1,530	$ 1,346

The weighted average estimated grant date fair value per share of stock options granted during the years ended December 31, 2015, 2014 and 2013 was $9.77 , $4.08 and $2.53 , respectively. At December 31, 2015, the total unamortized stock -based compensation expense of approximately $11.7 million is to be recognized over the stock options' remaining vesting terms of approximately 4.0 years (3.0 years on a weighted average basis). The total fair value of stock options that vested during the years ended December 31, 2015 and 2014 was $5.2 million and $1.8 million, respectively.

In July 2014, the Company granted stock options to purchase an aggregate of 1.2 million shares of common stock, which options contain a performance condition such that they would only become exercisable in the event that the Company's common stock was listed on a national securities exchange within one year from the date of grant. In accordance with authoritative guidance, the Company did not record any compensation expense associated with the grants until the performance condition was satisfied on June 30, 2015. As of December 31, 2014 and June 30, 2015, the total unamortized share -based compensation expense for these grants was $4.9 million. Upon the completion of the IPO on June 30, 2015, the Company immediately recognized cumulative compensation cost of $3.8 million for the grants as if the method had been applied since the date of grant using the required graded accelerated attribution method, and the Company will record compensation expense over the remainder of the four -year vesting period using this method. Stock options granted subsequent to July 2014 do not contain a performance condition.

The Company uses the Black -Scholes option -pricing model to estimate the fair value of stock -based awards on the date of grant. 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 highly 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. The Company only recently began to have publicly traded equity and has a limited operating history and a lack of Company -specific historical and implied volatility data, and therefore has estimated its stock price volatility based upon an index of the historical volatilities of a group of comparable publicly -traded medical device peer companies. The historical volatility data was computed using the historical daily closing prices for the selected peer companies' shares during the equivalent period of the calculated expected term of the Company's share -based awards. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

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. Historically, and until the June 30, 2015 completion of the Company's IPO, the fair value of the shares of common stock underlying the stock options has been the responsibility of and determined by the Company's Board of Directors. Because there had been no public market for the Company's common stock, the Board of Directors determined the fair value of common stock at the time of grant of the option by considering a number of objective and subjective factors including independent third ‑party valuations of the Company's common stock, sales prices of convertible preferred stock to unrelated third parties, operating and financial performance, the lack of liquidity of capital stock and general and industry specific economic outlook, among other factors. Subsequent to the date of the Company's IPO in June 2015, the Company has used the daily market prices in the determination of the fair value of its common stock.

Stock ‑based awards to employees

The weighted ‑average assumptions used to estimate the fair value of options granted to employees were as follows:

	Year ended December 31,		
	2015	2014	2013
Risk-free interest rate	1.77 %	1.91 %	1.25 %
Expected dividend yield	0.0 %	0.0 %	0.0 %
Expected volatility	56.0 %	60.7 %	63.1 %
Expected term (in years)	6.07	6.07	6.07

Forfeiture rate. The Company reduces employee 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.

The weighted ‑average per share exercise price of options granted to employees during the years ended December 31, 2015, 2014 and 2013 was $17.79 , $7.13 and $4.30 , respectively.

Stock ‑based awards to nonemployees

The fair values of stock ‑based awards made to nonemployees are remeasured at the end of the reporting period using the Black ‑Scholes option pricing model. The expected life for each option is determined based on the time remaining until the expiration of the option as of the date of remeasurement. Compensation expense for these share ‑based awards is determined by applying the recalculated fair values to the shares that have vested during a period.

Through December 31, 2015, in conjunction with various consulting agreements, the Company issued options to nonemployees to purchase 891,400 shares of common stock at exercise prices ranging from $0.25 to $25.91 per share. For the years ended December 31, 2015, 2014 and 2013, the Company recorded nonemployee stock ‑based compensation expense of $1.1 million, $0.3 million and $0.3 million, respectively.

Common stock reserved for future issuance

Common stock reserved for issuance is as follows (in thousands):

	As of December 31, 2015
Common stock warrant outstanding	6
Stock options issued and outstanding—2001 Plan	2,062
Stock options issued and outstanding—2011 Plan	3,037
Stock options issued and outstanding—2015 Plan	602
Employee stock purchase plan	374
Authorized for future stock awards or option grants	3,898
	9,979

9. Income taxes

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

	Year ended December 31,		
	2015	2014	2013
United States	$ (36,750)	$ (13,124)	$ (14,207)
Foreign	(1,538)	(915)	(14)
Total	$ (38,288)	$ (14,039)	$ (14,221)

The provision for income taxes was as follows (in thousands):

	December 31,		
	2015	2014	2013
Current:			
Federal	$ —	$ —	$ —
State	33	18	6
Foreign	—	—	—
	33	18	6
Deferred:			
Federal	—	—	—
State	—	—	—
Foreign	—	—	—
	—	—	—
Provision for income taxes	$ 33	$ 18	$ 6

The tax provision for the noncontrolling interest was $0 in 2015; therefore, no tax benefit or expense was allocated to the net loss attributable to noncontrolling interest.

The reconciliations of the U.S. federal statutory tax rate to the combined effective tax rate are as follows:

	Year ended December 31,		
	2015	2014	2013
Statutory rate of tax expense	34.0 %	34.0 %	34.0 %
State income taxes, net of federal benefit	3.5 %	3.3 %	4.3 %
Permanent and other items	(3.4)%	(1.9)%	(0.3)%
Deconsolidation of DOSE	(11.9)%	0.0 %	0.0 %
Nondeductible offering costs	0.0 %	(2.8)%	0.0 %
Research credits	4.6 %	9.6 %	9.9 %
Uncertain tax positions	(2.3)%	(4.7)%	(12.0)%
Change in tax rate	(0.2)%	(0.5)%	(4.8)%
Valuation allowance	(24.4)%	(35.7)%	(31.1)%
Effective tax rate	(0.1)%	1.3 %	0.0 %

Significant components of the Company's net deferred tax assets at December 31, 2015 and 2014 are as follows (in thousands):

	December 31,	
	2015	2014
Deferred tax assets:		
Net operating loss carryforwards	$ 45,870	$ 47,045
Tax credits	3,973	3,306
Depreciation and amortization	19,472	13,714
Stock-based compensation	3,749	1,439
Reserves and accruals	2,241	528
Other net	129	—
Total deferred tax assets	75,434	66,032
Valuation allowance	(75,434)	(66,032)
Net deferred tax assets	$ —	$ —

Based on the weight of available evidence, management has established a valuation allowance for all of the deferred tax assets as it is more likely than not that the deferred tax assets will not be realized. The net change in the valuation allowance was $9.4 million in 2015.

At December 31, 2015, the C ompany had approximately $118. 0 million, $98.0 million and $2.3 million of net operating loss carryforwards for federal, state and foreign purposes, respectively, available to offset future taxable income. The federal and state net operating loss carryforwards begin to expire in 2018 and 2016, respectively. A Japan tax loss of $0.7 million will expire in 2024 if not sooner utilized. The remaining foreign tax losses effectively do not expire.

At December 31, 2015, the Company had federal and state research and development credit carryforwards of $4.6 million and $5.1 million, respectively, which begin to expire in 2021 for federal purposes and carry over indefinitely for state purposes.

Utilization of the net operating loss and tax credit carryforwards will be subject to annual limitations under Sections 382 and 383 of the Internal Revenue Code of 1986 and similar state provisions due to several ownership changes that have occurred previously or that could occur in the future. These ownership changes will limit the amount of net operating loss and tax credit carryforwards and other deferred tax assets that can be utilized to offset future taxable income and tax. In general, all ownership changes as defined by 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. An analysis was performed by the Company which indicated that several ownership changes have occurred in previous years which created annual limitations on the Company's ability to utilize net operating loss and tax credit carryforwards. Such limitations will result in approximately $0.2 million of tax benefits related to net operating loss and tax credit

carryforwards that will expire unused. Accordingly, the related net operating loss and tax credit carryforwards have been removed from deferred tax assets accompanied by a corresponding reduction in the valuation allowance. Due to the existence of the valuation allowance, limitations created by future ownership changes, if any, will not impact the Company's effective tax rate.

The Company considers all earnings and profits of its foreign subsidiaries to be indefinitely reinvested. Due to losses incurred, there are no unrecorded income taxes associated with unrepatriated foreign earnings as of December 31, 2015.

A reconciliation of the beginning and ending amount of gross unrecognized tax benefits for 2015, 2014 and 2013, excluding interest and penalties, is as follows (in thousands):

	December 31,		
	2015	2014	2013
Balance at beginning of the year	$ 4,066	$ 3,272	$ 1,211
Additions (reductions) for tax positions—prior years	(284)	(27)	1,430
Additions for tax positions—current year	1,066	821	631
Balance at end of the year	$ 4,848	$ 4,066	$ 3,272

As of December 31, 2015, the r e would be no impact on the effective tax rate if the uncertain tax benefits were recognized .

The Company's policy is to recognize interest expense and penalties related to income tax matters as a component of income tax expense. There was no accrued interest and penalties associated with uncertain tax positions as of December 31, 2015 and 2014. It is not anticipated that there will be a significant change in the unrecognized tax benefits over the next 12 months.

Due to the Company's net operating loss carryforwards, its federal, state and foreign income tax returns are open to examination by the Internal Revenue Service and state jurisdictions for all years since inception.

10. Employee benefits

The Company sponsors a defined contribution plan pursuant to section 401(k) of the United States Internal Revenue Code that allows participating employees to contribute up to 100% of their salary, to an annual maximum of $17,500 in 2014 and $18,000 in 2015 ($23,000 and $24,000 in 2014 and 2015, respectively, for employees over the age of 50). The Company may contribute at its discretion. To date, the Company has only made "qualified nonelective contributions" to maintain compliance with IRS regulations. No plan contributions were made by the Company in 2015 , 2014 and 2013.

11. Commitments and contingencies

The Company, from time to time, is involved in legal proceedings or regulatory encounters or other matters in the ordinary course of business that could result in unasserted or asserted claims or litigation. At December 31, 2015 and 2014, there were no matters for which the negative outcome was considered probable or estimable, and, as a result, no amounts have been accrued at either date.

Operating leases

The Company leases its main headquarters and manufacturing facility and facilities for its foreign subsidiaries. Certain of the Company's leases contain renewal options, rent escalation clauses, and/or landlord incentives. Rent expense for noncancelable operating leases with scheduled rent increases and/or landlord incentives is recognized on a straight-line basis over the lease term beginning with the lease commencement date, or the date the Company takes control of the leased space, whichever is sooner. The excess of straight-line rent expense over scheduled payment amounts and landlord incentives is recorded as a deferred rent liability.

The current main facility leases in Laguna Hills, California for 23,915 square feet expire on September 3 0 , 2016.

In June 2015, the Company entered into a sublease for an approximately 37,700 square foot facility located in San Clemente, California effective September 1, 2015, and a five -year lease for the facility that takes effect January 1, 2017 upon expiration of the sublease. This facility is intended to become the Company's main headquarters and manufacturing facility. Rent under the direct lease begins on January 1, 2017 at approximately $42,000 per month, with rent for the second and third months abated, and the annual rent payments increase beginning on January 1, 2018 at percentages ranging from 2.5% to 3.5% . The direct lease agreement contains an option to extend the lease for up to two additional three -year periods at market rates. The direct lease landlord has agreed to provide the Company with a tenant improvement allowance on January 1, 2017 in the amount of the cost of any leasehold improvements, not to exceed approximately $264,000 .

The Company's foreign subsidiaries lease office space totaling less than 2,000 square feet.

The Company recorded deferred rent of $149,000 and $57,000 as of December 31, 2015 and 2014, respectively, in conjunction with its facilities lease agreements. Rent expense was $0.6 million, $0.3 million and $0.3 million for the years ended December 31, 2015, 2014 and 2013, respectively.

Future minimum payments under the aforementioned noncancelable operating leases for each of the five succeeding years are as follows (in thousands):

2016	$	585
2017		469
2018		551
2019		569
2020		582
Thereafter		596
	$	3,352

Purchase commitment

The Company is a party to various purchase arrangements related to components used in production and research and development activities. As of December 31, 2015, the Company had noncancelable, firm purchase commitments with certain vendors totaling approximately $ 2.6 million, due within one year. There are no material purchase commitments 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 Agreement, Glaukos agreed to pay to the University the sum of $2.7 million via five payments during the course of 2015, and, beginning with sales on or after January 1, 2015, to pay 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 $500,000 . This ongoing product payment terminates on the date that the last of the Patent Rights expires, which is currently expected to be in 2022. In 2015, the Company recorded approximately $1.8 million in cost of sales in connection with this product payment obligation. The $2.7 million obligation, net of imputed interest of $0.1 million, was accrued as of December 31, 2014 and charged to cost of sales in the year ended December 31, 2014. Under the terms of the UC Agreement, the payments comprising the $2.7 million obligation were due within 60 days of the IPO, and, accordingly, the Company paid the remaining balance due of $1.8 million prior to August 29, 2015.

Transcend Medical Litigation Settlement

On October 29, 2015, the Company entered into a settlement agreement with Transcend Medical, Inc. (Transcend) to resolve the patent litigation then pending between the companies before the U.S. District Court for the District of

Delaware. Under the settlement agreement, the Company granted Transcend a covenant not to sue Transcend for patent infringement in connection with Transcend's CyPass Micro-Stent devices, appliers and delivery systems. In exchange, Transcend granted the Company a covenant not to challenge the validity or enforceability of any Glaukos patent and will make quarterly payments to the Company equal to 1% of future net sales of the CyPass Micro-Stent devices until April 8, 2022 or up to a maximum aggregate payment amount of $6.0 million. In connection with the settlement agreement, the parties filed a joint stipulation of dismissal with prejudice of all of their respective claims against each other in this matter, with each party responsible for its own legal expenses. The court dismissed the matter with prejudice on October 29, 2015 and the need for the trial that was scheduled to begin November 2, 2015 was eliminated. In connection with entering into the settlement agreement, the Company agreed to pay the Regents 33% of any payments the Company receives from Transcend pursuant to the settlement agreement

12. Variable interest entity

In October 2009, the Company formed a wholly -owned subsidiary, DOSE Medical Corporation and in April 2010, the Company distributed all of its shares of common stock of DOSE via a stock dividend to the Company's stockholders of record as of the close of business on March 31, 2010. Since its formation, the Company had provided DOSE with a small number of leased employees, management services and space, all of which had been charged to DOSE and pursuant to written agreements between the parties. Additionally, the Company had provided DOSE the cash required to fund its operations that, together with accrued interest and charges for the aforementioned services, the Company had recorded in an intercompany receivable account. Up until the transaction on June 30, 2015 described below, the Company had accounted for DOSE as a variable interest entity in which it had a variable interest in all reporting periods since the formation of DOSE. Accordingly, the Company's consolidated financial statements include the accounts of DOSE, with all intercompany balances eliminated and with the deficit balance of DOSE's net assets reflected as noncontrolling interest, up to but excluding June 30, 2015.

On June 30, 2015, the Company completed a transaction initially executed in July 2014, the closing of which was contingent upon the successful completion of an IPO. Pursuant to the terms of the asset purchase agreement, the Company acquired from DOSE certain assets, including the *iDose* product line, in exchange for payment of $15.0 million in cash and the elimination of the $10.9 million intercompany receivable owed by DOSE to the Company as of the closing date. In addition to the asset purchase agreement, the parties agreed to an amended and restated patent license agreement and an amended and restated transition services agreement that provides for limited support from the Company to DOSE for a period of up to three years. Either party can terminate the transition services agreement upon adequate written notice. Two members of the Company's board of directors currently serve on the board of directors of DOSE.

The Company has reconsidered its relationship with DOSE as a result of the transaction and has determined that the Company is no longer considered to be the primary beneficiary with the power to direct operations and the right to receive benefits/absorb losses of DOSE; therefore, upon the close of the transaction, the Company derecognized DOSE and will no longer consider it a consolidated entity in its financial statements. Accordingly, in the three months ended June 30, 2015, the Company recorded a charge to other expense in the amount of $25.7 million to reflect the deconsolidation of DOSE' non -glaucoma related assets and noncontrolling interest.

The carrying amount and classification of DOSE's assets and liabilities that are included in the accompanying consolidated balance sheets are as follows (in thousands):

	December 31,	
	2015	2014
Cash and cash equivalents	$ —	$ 9
Prepaid expenses	—	16
Property and equipment, net	—	255
Total assets of DOSE	$ —	$ 280

	December 31, 2015	2014
Accounts payable and accrued liabilities	$ —	$ 160
Liability to Glaukos Corporation	—	9,720
Total liabilities of DOSE	$ —	$ 9,880

Consolidation of DOSE's results of operations included the following (in thousands):

	Year ended December 31, 2015	2014	2013
Selling, general & administrative	$ 105	$ 243	$ 208
Research and development	890	1,557	1,262
Interest expense	85	156	141
Net loss of DOSE	$ 1,080	$ 1,956	$ 1,611

Consolidation of DOSE's cash flows included the following (in thousands):

	Year ended December 31, 2015	2014	2013
Cash used in operating activities	$ (1,134)	$ (1,271)	$ (1,471)
Cash used in investing activities	(33)	(39)	(108)
Cash provided by financing activities	1,158	1,315	1,569
(Decrease) increase in cash and cash equivalents of DOSE	$ (9)	$ 5	$ (10)

13. Business segment information

Operating segments are identified as components of an enterprise about which segment discrete financial information is available for evaluation by the chief operating decision maker in making decisions regarding resource allocation and assessing performance. The Company operates its business on the basis of one reportable segment—ophthalmic medical devices.

Geographic net sales information (in thousands)	Year ended December 31, 2015	2014	2013
United States	$ 67,698	$ 42,932	$ 19,507
International	4,002	2,655	1,439
Total net sales	$ 71,700	$ 45,587	$ 20,946

	Property and equipment, net As of December 31,			Depreciation and amortization Year ended December 31,			Capital expenditures Year ended December 31,		
	2015	2014	2013	2015	2014	2013	2015	2014	2013
United States	$2,012	$ 1,784	$ 1,684	$ 4,180	$ 4,149	$ 1,089	$ 972	$ 749	$ 888
International	142	166	182	87	82	68	62	68	8
Total	$2,154	$ 1,950	$ 1,866	$ 4,267	$ 4,231	$ 1,157	$1,034	$ 817	$ 896

14. Selected Quarterly Financial Information (Unaudited)

(in thousands, except per share amounts)	Three months ended March 31, 2015	June 30, 2015	September 30, 2015	December 31, 2015
Net sales	$ 14,666	$ 17,754	$ 19,004	$ 20,276
Cost of sales	2,794	3,281	3,319	3,594
Gross profit	11,872	14,473	15,685	16,682
Operating expenses:				
Selling, general and administrative	7,816	12,516	11,237	12,392
Research and development	5,240	7,339	6,173	6,295
Total operating expenses	13,056	19,855	17,410	18,687
Loss from operations	(1,184)	(5,382)	(1,725)	(2,005)
Loss on deconsolidation of DOSE	—	(25,685)	—	—
Total other expense, net	(278)	(1,445)	(332)	(252)
Provision for income taxes	—	—	—	33
Net loss	$ (1,462)	$ (32,512)	$ (2,057)	$ (2,290)
Net loss attributable to Glaukos Corporation	$ (966)	$ (31,928)	$ (2,057)	$ (2,290)
Net loss per share attributable to Glaukos Corporation stockholders [1]:				
Basic	$ (0.40)	$ (10.96)	$ (0.06)	$ (0.07)
Diluted	$ (0.40)	$ (10.96)	$ (0.07)	$ (0.07)

(in thousands, except per share amounts)	Three months ended March 31, 2014	June 30, 2014	September 30, 2014	December 31, 2014
Net sales	$ 8,249	$ 11,099	$ 12,126	$ 14,113
Cost of sales [2]	1,944	2,339	2,246	4,889
Gross profit	6,305	8,760	9,880	9,224
Operating expenses:				
Selling, general and administrative [3]	5,948	6,582	6,669	8,936
Research and development	4,383	4,422	5,093	5,307
Total operating expenses	10,331	11,004	11,762	14,243
Loss from operations	(4,026)	(2,244)	(1,882)	(5,019)
Total other expense, net	(311)	(250)	(84)	(223)
Provision for income taxes	2	—	5	11
Net loss	$ (4,339)	$ (2,494)	$ (1,971)	$ (5,253)
Net loss attributable to Glaukos Corporation	$ (3,957)	$ (2,074)	$ (1,489)	$ (4,606)
Net loss per share, basic and diluted, attributable to Glaukos Corporation stockholders [1]	$ (1.83)	$ (0.90)	$ (0.64)	$ (1.94)

(1) Net loss per share is computed independently for e ach of the quarters presented. Therefore, the sum of the quarterly per-share amounts will not necessar i ly equal the annual per share amount.

(2) Includes a $2.6 million charge in the three months ended December 31, 2014 associated with the Company's December 2014 agreement with The Regents of the University of California.

(3) Includes approximately $1.2 million in costs in the three months ended December 31, 2014 related to the Company's efforts to prepare for its IPO.

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

None.

ITEM 9A. CONTROL S 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 report. 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, 2015 .

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 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Exemption from Management's Report and Auditor Attestation on Internal Control Over Financial

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for newly public companies and emerging growth companies .

ITEM 9B. OTHER INFORMATION

None.

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 website, 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 on our website at www.glaukos.com.

The remaining information required by this Item 10 will be included in our Proxy Statement for the 2016 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, 2015, and is incorporated herein by reference.

ITEM 1 1 . EXECUTIVE COMPENSATION

The information required by this Item 11 will be included in our Proxy Statement for the 2016 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, 2015, 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 2016 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, 2015, 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 2016 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, 2015, and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by this Item 14 will be included in our Proxy Statement for the 2016 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, 2015, and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, 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 the y 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 (following the signatures page of this report) are filed, furnished or incorporated by reference as part of this Annual Report on Form 10-K.

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 Laguna Hills, State of California, on March 14, 2016.

GLAUKOS CORPORATION

By: /s/ Thomas W. Burns
Thomas W. Burns
Chief Executive Officer and President

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.

Signature	Title	Date
/s/ Thomas W. Burns Thomas W. Burns	Chief E xecutive Officer, President and Director (Principal Executive Officer)	March 14 , 2016
/s/ Richard L. Harrison Richard L. Harrison	Treasurer, Chief Financial Officer and Secretary (Principal Accounting and Financial Officer)	March 14 , 2016
/s/ William J. Link William J. Link, Ph.D.	Chairman of the Board	March 14 , 2016
/s/ Olav B. Bergheim Olav B. Bergheim	Director	March 14 , 2016
/s/ Mark J. Foley Mark J. Foley	Director	March 14 , 2016
/s/ David F. Hoffmeister David F. Hoffmeister	Director	March 14 , 2016
/s/ Gilbert H. Kliman Gilbert H. Kliman, M.D.	Director	March 14 , 2016
/s/ Jonathan T. Silverstein Jonathan T. Silverstein	Director	March 14 , 2016
/s/ Marc A. Stapley Marc A. Stapley	Director	March 14 , 2016
/s/ Aimee S. Weisner Aimee S. Weisner	Director	March 14 , 2016

INDEX TO EXHIBITS

Exhibit Number	Description
3.1	Restated Certificate of Incorporation of the Registrant (incorporated by referenced to Exhibit 3.1 to the 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 3.2 to the Form 8 -K (File No. 001 -37463) filed on June 30, 2015).
10.1	Fourth Amended and Restated Investors' Rights Agreement, dated as of January 25, 2011, by and among the Registrant and the stockholders named therein (incorporated by reference to Exhibit 10.1 to the Registration Statement on Form S -1 (No. 333 -204091) filed on May 12, 2015).
10.2	Amendment No. 1 to the Fourth Amended and Restated Investors' Rights Agreement, dated as of January 22, 2013, by and among the Registrant and the stockholders named therein (incorporated by reference to Exhibit 10.2 to the Registration Statement on Form S -1 (No. 333 -204091) filed on May 12, 2015).
10.3	Amendment No. 2 to the Fourth Amended and Restated Investors' Rights Agreement, dated as of July 10, 2014, by and among the Registrant and the stockholders named therein (incorporated by reference to Exhibit 10.3 to the Registration Statement on Form S -1 (No. 333 -204091) filed on May 12, 2015).
10.4	Form of Warrant to Purchase Series D Preferred Stock (incorporated by reference to Exhibit 10.6 to the Registration Statement on Form S -1 (No. 333 -204091) filed on May 12, 2015).
10.5	Amendment to Series D Warrants, dated as of July 10, 2014 (incorporated by reference to Exhibit 10.7 to the Registration Statement on Form S -1 (No. 333 -204091) filed on May 12, 2015).
10. 6 +	Form of Director and Executive Officer Indemnification Agreement (incorporated by reference to Exhibit 10.8 to the Registration Statement on Form S -1 (No. 333 -204091) filed on May 12, 2015).
10.7+	2001 Stock Option Plan (incorporated by reference to Exhibit 10.9 to the Registration Statement on Form S -1 (No. 333 -204091) filed on May 12, 2015).
10.8+	Notice of Incentive Stock Option Grant and Stock Option Agreement under the 2001 Stock Option Plan (incorporated by reference to Exhibit 10.10 to the Registration Statement on Form S -1 (No. 333 -204091) filed on May 12, 2015).
10.9+	Notice of Non -Statutory Stock Option Grant and Stock Option Agreement under the 2001 Stock Option Plan (incorporated by reference to Exhibit 10.11 to the Registration Statement on Form S -1 (No. 333 -204091) filed on May 12, 2015).
10.10+	2011 Stock Plan (incorporated by reference to Exhibit 10.12 to the Registration Statement on Form S -1 (No. 333 -204091) filed on May 12, 2015).
10.11+	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 (No. 333 -204091) filed on May 12, 2015).
10.12+	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 (No. 333 -204091) filed on May 12, 2015).
10.13+	2015 Omnibus Incentive Compensation Plan (incorporated by reference to Exhibit 10.15 to Amendment No. 2 to the Registration Statement on Form S -1 (No. 333 -204091) filed on June 15, 2015).
10.14+	2015 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.16 to Amendment No. 2 to the Registration Statement on Form S -1 (No. 333 -204091) filed on June 15, 2015).
10.15+	Thomas W. Burns Offer Letter dated July 10, 2014 (incorporated by reference to Exhibit 10.17 to the Registration Statement on Form S -1 (No. 333 -204091) filed on May 12, 2015).
10.16+	Thomas W. Burns Executive Severance and Change in Control Agreement dated July 10, 2014 (incorporated by reference to Exhibit 10.18 to the Registration Statement on Form S -1 (No. 333 -204091) filed on May 12, 2015).

Exhibit Number	Description
10.17+	Chris M. Calcaterra Offer Letter dated July 10, 2014 (incorporated by reference to Exhibit 10.19 to the Registration Statement on Form S -1 (No. 333 -204091) filed on May 12, 2015).
10.18+	Chris M. Calcaterra Executive Severance and Change in Control Agreement dated July 10, 2014 (incorporated by reference to Exhibit 10.20 to the Registration Statement on Form S -1 (No. 333 -204091) filed on May 12, 2015).
10.19+	Richard L. Harrison Offer Letter dated July 10, 2014 (incorporated by reference to Exhibit 10.21 to the Registration Statement on Form S -1 (No. 333 -204091) filed on May 12, 2015).
10.20+	Richard L. Harrison Executive Severance and Change in Control Agreement dated July 10, 2014 (incorporated by reference to Exhibit 10.22 to the Registration Statement on Form S -1 (No. 333 -204091) filed on May 12, 2015).
10.21	Standard Business Park Lease—Multi -Tenant, dated as of November 9, 2009, by and between the Registrant and Laguna Cabot Road Business Park, LP (incorporated by reference to Exhibit 10.23 to the Registration Statement on Form S -1 (No. 333 -204091) filed on May 12, 2015).
10.22	Second Amendment and Lease Consolidation (regarding suites 103, 104 and 105), dated as of September 30, 2011, by and between the Registrant and Laguna Cabot Road Business Park, LP (incorporated by reference to Exhibit 10.24 to the Registration Statement on Form S -1 (No. 333 -204091) filed on May 12, 2015).
10.23*	Third Amendment to Lease (regarding Suites 103, 104 and 105), dated as of November 23, 2015, by and between the Registrant and Laguna Cabot Road Business Park, LP.
10.24	Asset Purchase Agreement, dated as of July 10, 2014, by and between the Registrant and DOSE Medical Corporation (incorporated by reference to Exhibit 10.25 to the Registration Statement on Form S -1 (No. 333 -204091) filed on May 12, 2015).
10.25	Amended and Restated Revolving Credit And Term Loan Agreement, dated as of February 23, 2015, by and between the Registrant and Comerica Bank as Administrative Agent, Sole Lead Arranger and Sole Bookrunner (incorporated by reference to Exhibit 10.26 to the Registration Statement on Form S -1 (No. 333 -204091) filed on May 12, 2015).
10.26	Form of Swing Line Note (incorporated by reference to Exhibit 10.27 to the Registration Statement on Form S -1 (No. 333 -204091) filed on May 12, 2015).
10.27	Form of Revolving Credit Note (incorporated by reference to Exhibit 10.28 to the Registration Statement on Form S -1 (No. 333 -204091) filed on May 12, 2015).
10.28	Form of Term Loan Note (incorporated by reference to Exhibit 10.29 to the Registration Statement on Form S -1 (No. 333 -204091) filed on May 12, 2015).
10.29	Form of Draw -to Term Loan Note (incorporated by reference to Exhibit 10.30 to the Registration Statement on Form S -1 (No. 333 -204091) filed on May 12, 2015).
10.30	Amended and Restated Security Agreement dated as of February 23, 2015 by and among the Registrant, and such other entities that become parties thereto, and Comerica Bank as Administrative Agent for an on behalf of the Lenders (incorporated by reference to Exhibit 10.31 to the Registration Statement on Form S -1 (No. 333 -204091) filed on May 12, 2015).
10.31	Warrant issued to Comerica Bank dated February 23, 2015 (incorporated by reference to Exhibit 10.32 to the Registration Statement on Form S -1 (No. 333 -204091) filed on May 12, 2015).
10.32	Warrant issued to Square 1 Bank dated February 23, 2015 (incorporated by reference to Exhibit 10.33 to the Registration Statement on Form S -1 (No. 333 -204091) filed on May 12, 2015).
10.33	Sublease Agreement made as of June 10, 2015, by and between the Registrant and Boston Scientific Corporation (incorporated by reference to Exhibit 10.34 to Amendment No. 2 to the Registration Statement on Form S -1 (No. 333 -204091) filed on June 15, 2015).
10.34	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 (No. 333 -204091) filed on June 15, 2015).

Exhibit Number	Description
10.35	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 Form 8 -K (File No. 001 -37463) filed on June 30, 2015).
10.36	Amended and Restated Transition Services Agreement, by and between the Registrant and DOSE Medical Corporation, dated as of June 30, 2015 (incorporated by reference to Exhibit 10.2 to the Form 8 -K (File No. 001 -37463) filed on June 30, 2015).
21*	Subsidiaries of Glaukos Corporation
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
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

+ Indicates a management contract or compensatory plan or arrangement.

* Filed Herewith.

** Furnished Herewith.

Exhibit 10.23

THIRD AMENDMENT TO LEASE

This Third Amendment to Lease (" **Third Amendment** ") is dated for reference purposes the 23rd day of November, 2015, and is entered into by and between Laguna Cabot Road Business Park, LP (" **Landlord** "), and Glaukos Corporation (" **Tenant** "), with reference to the following recitals.

RECITALS

A. On or about October 1, 2005, Landlord and Tenant entered into a Standard Business Park Lease — Multi-Tenant (the " **Original Lease** ") for that certain premises of approximately 20,800 square feet in size and commonly known as Suites 103, 104 and 105, 26051 Merit Circle, Laguna Hills, California (the " **Premises** "). On or about October 8, 2008, Landlord and Tenant entered into a First Amendment to Lease (the " **First Amendment** ").On or about September 30, 2011, Landlord and Tenant entered into a Second Amendment to Lease (the " **Second Amendment** "). The Original Lease as modified by the First and Second Amendment is hereinafter referred to as the "Lease",

B, Tenant and Landlord acknowledge and agree that all prior tenant improvements and other work to be performed by Landlord under the Lease have been completed and accepted by Tenant, there are no defaults under the Lease by either Landlord or Tenant, all obligations of Landlord and Tenant accruing prior to the date of this amendment have been performed by Landlord and Tenant and that the Existing Premises are being leased in its "as is", "where is" "with all faults" condition.

C. Landlord and Tenant wish to amend the Lease to extend the term and modify the rent and other terms and conditions as set forth below.

TERMS AND CONDITIONS

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

1. Term of Lease . The Expiration Date shall be extended to September 30, 2016.

2. Monthly Base Rent . The Monthly Base Rent shall be as follows:

April 1, 2016 through September 30, 2016: $28,080.00

3. CAM Charge . Beginning April 1, 2016; the CAM Charge defined in Section 1.1n of the Tenant Specific Terms of the Lease shall remain $2,080,00.

4. Security Deposit . Tenant's security deposit shall remain amount currently in possession of Landlord.

5. Brokers. Tenant and Landlord each represent and warrant to the other that neither has had any dealings or entered into any agreements with any person, entity, broker or finder other than as specified in Exhibit A in connection with the negotiation of this Third Amendment, and no other broker, person, or entity is entitled to any commission or finder's fee in connection with the negotiation of this Third Amendment, and Tenant and Landlord each agree to indemnify, defend and hold the other harmless from and against any claims, damages, costs, expenses, attorneys' fees or liability for compensation or charges which may be claimed by any such unnamed broker, finder or other similar party by reason of any dealings, actions or agreements of the indemnifying party.

6. Conflict. If there is a conflict between the terms and conditions of this Third Amendment and the terms and conditions of the Lease, the terms and conditions of this Third Amendment shall control. Except as modified by this Third Amendment, the terms and conditions of the Lease shall remain in full force and effect. Capitalized terms included in this Third Amendment shall have the same meaning as capitalized terms in the Lease unless otherwise defined herein.

7. Representations. Tenant hereby acknowledges and agrees that the Lease is in full force and effect, Landlord is not currently in default under the Lease, and, to the best of Tenant's knowledge, no event has occurred which, with the giving of notice or the passage of time, or both, would ripen into Landlord's default under the Lease. Landlord hereby acknowledges and agrees that the Lease is in full force and effect, Tenant is not currently in default under the Lease, and, to the best of Landlord's knowledge, no event has occurred which, with the giving of notice or the passage of time, or both, would ripen into Tenant's default under the Lease. The Lease, as hereby amended. contains all agreements of the parties with respect to the lease of the Premises. No prior or contemporaneous agreement or understanding pertaining to the Lease, as hereby amended, shall be effective.

8. Authority. The persons executing this Third Amendment on behalf of the parties hereto represent and warrant that they have the authority to execute this Third Amendment on behalf of said parties and that said parties have authority to enter into this Third Amendment.

9. Confidentiality. Tenant acknowledges and agrees that the terms of this Third Amendment are confidential and constitute proprietary information of Landlord. Disclosure of the terms hereof could adversely affect the ability of Landlord to negotiate other leases with respect to the Project and may impair Landlord's relationship with other Tenants of the Project. Tenant agrees that it and its partners, officers, directors, employees, brokers, and attorneys, if any, shall not disclose the terms and conditions of this Third Amendment to any other person or entity without the prior written consent of Landlord which may be given or withheld by Landlord, in Landlord's sole discretion. It is understood and agreed that damages alone would be an inadequate remedy for the breach of this provision by Tenant, and Landlord shall also have the right to seek specific performance of this provision and to seek injunctive relief to prevent its breach or continued breach.

10. Counterparts. This Third Amendment may be executed in counterparts. Each counterpart shall be deemed an original, and all counterparts shall be deemed the same instrument with the same effect as if all parties hereto had signed the same signature page. A signed copy of this Third Amendment delivered by facsimile, e-mail, or other means of electronic transmission

shall be deemed to have the same legal effect as delivery of an original signed copy of this Third Amendment. This Third Amendment shall become binding upon Landlord only when fully executed by all parties and when Landlord has delivered a fully executed copy of this Third Amendment to Tenant.

11. Accessibility; Americans with Disabilities Act. (a) The Premises have not undergone an inspection by a Certified Access Specialist (CASp); (b) Since compliance with the Americans with Disabilities Act (ADA) is dependent upon Tenant's specific use of the Premises, Landlord makes no warranty or representation as to whether or not the Premises, the Building, or the Project comply with ADA or any similar legislation. In the event that Tenant's use of the Premises requires modifications or additions to the Premises, the Building or the Project in order to be in ADA compliance, Tenant agrees to make any such necessary modifications and/or additions at Tenant's expense.

12. Energy Use. Landlord shall have the right to require Tenant to provide Landlord with copies of bills from electricity, natural gas or similar energy providers (collectively, " **Energy Providers** ") Tenant receives from Energy Providers relating to Tenant's energy use at the Premises (" **Energy Bills** ") within ten (10) days after Landlord's written request. In addition, Tenant hereby authorizes Landlord to obtain copies of the Energy Bills directly from the Energy Provider(s), and Tenant hereby authorizes each Energy Provider to provide Energy Bills and related usage information directly to Landlord without Tenant's consent. From time to time within ten (10) days after Landlord's request, Tenant shall execute and deliver to Landlord an agreement provided by Landlord authorizing the Energy Provider(s) to provide to Landlord Energy Bills and other information relating to Tenant's energy usage at the Premises.

IN WITNESS WHEREOF, the parties hereby execute this Third Amendment as of the date first written above.

LANDLORD

Laguna Cabot Road Business Park, LP

By: Davis Realty Partners LLC,
a Delaware limited liability company,
Its: Authorized Signer

By: /s/ Mark T. Buchanan
Mark T. Buchanan
Its: Principal

TENANT

Glaukos Corporation

By: /s/ T. W. Burns

Its: President & CEO

By: /s/ Richard L. Harrison

Its: CFO

* If Tenant is a corporation, the authorized officers must sign on behalf of the corporation and indicate the capacity in which they are signing. The Lease must be executed by the president or vice president and the secretary or assistant secretary, unless the bylaws or a resolution of the board of directors shall otherwise provide, in which event the bylaws or a certified copy of the resolution, as the case may be, must be attached to this Lease.

Exhibit A

Agency Disclosure

REPRESENTATION ACKNOWLEDGEMENT

Date:	11/16/15
Landlord:	Laguna Cabot Road Business Park, LP
Tenant:	Glaukos Corporation
Property Name:	Laguna Cabot Business Park
Street Address, City, State:	**26051 Merit Circle, Suites 103 /104/ 105, Laguna Hills, CA**
Further described as:	**a suite(s) within a multi-tenant business park**

The State of California requires that real estate agents provide the attached Disclosure Regarding Real Estate Agency Relationship. Please read it carefully.

With regard to the above-referenced transaction, please acknowledge below the following agency relationships:

Davis Broker, Inc. (CalBRE #01824698) is the listing agent of
☐ **the landlord exclusively** ; or ☐ **both the tenant and landlord**

Associate Licensee

By: /s/ Eileen Adams
Name: Eileen Adams (CalBRE # 01844171)

Tenant

By: /s/ T. W. Burns

Name: Thomas W. Burns

Title: President & CEO

Note: The State of California uses the following terms interchangeably:
Seller = Landlord = Lessor; Buyer = Tenant = Lessee

Please note that the terms "Seller" and "Buyer" are defined by the CA Civil Code to include a lessor and lessee, respectively.

If you are a Listing Agent - you must deliver the form to the seller/lessor before entering into the listing agreement. If the buyer/lessee is not represented by an agent, you must also deliver the form to it within one business day after receiving an offer from the buyer/lessee.

If you are the Buyer's Agent - you must deliver the form in the buyer/lessee as soon as the buyer/lessee seeks your services, but in any event before the buyer/lessee signs an offer. In addition, you must also deliver the form to the seller/lessor before or concurrently with presenting an offer.

DISCLOSURE REGARDING REAL ESTATE AGENCY RELATIONSHIP

When you enter into a discussion with a real estate agent regarding a real estate transaction, you should from the outset understand what type of agency relationship or representation you wish to have with the agent in the transaction.

SELLER'S AGENT

A Seller's agent under a listing agreement with the Seller acts as the agent for the Seller only. A Seller's agent or a subagent of that agent has the following affirmative obligations:

To the Seller : A fiduciary duty of utmost care, integrity, honesty, and loyalty in dealings with the Seller.

To the Buyer and the Seller :

(a) Diligent exercise of reasonable skill and care in performance of the agent's duties.

(b) A duty of honest end fair dealing and good faith.

(c) A duty to disclose all facts known to the agent materially affecting the value or desirability of the property that are not known to, or within the diligent attention and observation of, the parties.

An agent is not obligated to reveal to either party any confidential information obtained from the other pally that does not involve the affirmative duties set forth above.

BUYER'S AGENT

A selling agent can, with a Buyer's consent, agree to act as agent for the Buyer only. In these situations, the agent is not the Seller's agent, even if by agreement the agent may receive compensation for services rendered, either in full or in part from the Seller. An agent acting only for a Buyer has the following affirmative obligations:

To the Buyer : A fiduciary duty of utmost care, integrity, honesty, and loyalty in dealings with the Buyer.

To the Buyer and the Seller :

(a) Diligent exercise of reasonable skill and care in performance of the agent's duties.

(b) A duty of honest and fair dealing and good faith.

(c) A duty to disclose all facts known to the agent materially affecting the value or desirability of the property that are not known to, or within the diligent attention and observation of, the parties. An agent is not obligated to reveal to either party any confidential information obtained from the other party that does riot involve the affirmative duties set forth above.

AGENT REPRESENTING BOTH SELLER AND BUYER

A real estate agent, either acting directly or through one or more associate licensees, can legally be the agent of both the Seller and the Buyer in a transaction, but only with the knowledge and consent of both the Seller and the Buyer. In a dual agency situation, the agent has the following affirmative obligations to both the Seller and the Buyer:

(a) A fiduciary duty of utmost care, integrity, honesty and loyalty in the dealings with either the Seller or he Suva-.

(b) Other duties to the Seller and the Buyer as stated above in their respective sections.

In representing both Seller and Buyer, the agent may not, without the express permission of the respective party, disclose to the other party that the Seller will accept a price less than the listing price or that the Buyer will pay a price greeter than the price offered. The above duties of the agent in a real estate transaction do not relieve a Seller or Buyer from the responsibility to protect his or her own interests. You should carefully read all agreements to assure that they adequately express your understanding of the transaction. A real estate agent is a person qualified to advise about real estate. If legal or tax advice is desired, consult a competent professional. Throughout your real property transaction you may receive more than one disclosure form, depending upon the number of agents assisting in the transaction. The law requires each agent with whom you have more than a casual relationship to present you with this disclosure form. You should read its contents each time it is presented to you, considering the relationship between you and the real estate agent in your specific transaction. This disclosure form includes the provisions of Sections 2079.13 to 2079.24, inclusive, of the Civil Code set forth on the reverse hereof. Read it carefully.

DAVIS BROKER, INC. (CalBRE #01824628)

Agent

Associate Licensee Signature (Date)

Associate Licensee Printed Name

Buyer/Lessee Signature (Date)

Buyer/Lessee Printed Name

Seller/Lessor Signature (Date)

Seller/Lessor Printed Name

2079.13. As used in Sections 2079.14 in 2079.24, inclusive, the following terms have the following meanings:

(a) "Agent" means a person acting under provisions of Title 9 (commencing with Section 2295) in a real property transaction, and includes a person who is licensed as a real estate broker under Chapter 3 (commencing with Section 10130) of Part 1 of Division 4 of the Business and Professions Code, and under whose license a listing is executed or an offer to purchase is Obtained.

(b) "Associate licensee" means a person who is licensed as a real estate broker or salesperson under Chapter 3 (commencing with Section 10130) of Part 1 of Division 4 of the Business and Professions Code and who is either licensed under a broker or has entered into a written contract with a broker to act as the broker's agent in connection with acts requiring a real estate license and to function under the broker's supervision in the capacity of an associate licensee. The agent in the real property transaction bears responsibility for his or her associate licensees who perform as agents of the agent. When an associate licensee owes a duty to any principal, or to any buyer or seller who is not a principal, in a real property transaction, that duty is equivalent to the duty owed to that party by the broker for whom the associate licensee functions.

(c) "Buyer" means a transferee in a real property transaction, and includes a person who executes an offer to purchase real property from a seller through an agent, or who seeks the services of an agent in more than a casual, transitory, or preliminary manner, with the object of entering into a real property transaction. "Buyer" includes vendee or lessee.

(d) "Dual agent" means an agent acting, either directly or through an associate licensee, as agent for both the seller and the buyer in a real property transaction.

(e) "Listing agreement" means a contract between an owner of real property and an agent, by which the agent has been authorized to sell the real property or to find or obtain a buyer.

(f) "Listing agent" meets a person who has obtained a listing of real property to act as an agent for compensation.

(g) "Listing price" is the amount expressed in dollars specified in the listing for which the seller is willing to sell the real property through the listing agent.

(h) "Offering price" is the amount expressed in dollars specified in an offer to purchase for which the buyer is willing to buy the real property.

(i) "Offer to purchase" means a written contract executed by a buyer acting through a selling agent which becomes the contract for the sale of the real property upon acceptance by the seller.

(j) "Real property" means any estate specified by subdivision (1) or (2) of Section 761 in property which constitutes or is improved with one to four dwelling units, any leasehold in this type of property exceeding one year's duration, and mobile homes, when offered for sale or sold through an agent pursuant to the authority contained in Section 10131.6 of the Business and Professions Code.

(k) "Real property transaction" means in transaction for the sale of real property in which an agent is employed by one or more of the principals to act in that transaction, and includes a listing or an offer to purchase.

(l) "Sell," "sale," or "sold' refers to a transaction for the transfer of real property from the seller to the buyer, and includes exchanges of real property between the seller and buyer, transactions for the creation of a real property sales contract within the meaning of Section 2985, and transactions for the creation of a leasehold exceeding one year's duration.

(m) "Seller" means the transferor in a real property transaction, and includes an owner who lists real property with an agent, whether or not a transfer results, or who receives an offer to purchase real property of which he or she is the owner from an agent on behalf of another. "Seller" includes both a vendor and a lessor.

(n) "Selling agent" means a listing agent who acts alone, or an agent who acts in cooperation with a listing agent, and who sells or finds and obtains a buyer for the real property, or an agent who locates property for a buyer or who finds a buyer for a property for which no listing exists and presents an offer in purchase to the seller.

(o) "Subagent" means a person to whom an agent delegates agency powers as provided in Article 5 (commencing with Section 2349) of Chapter 1 of Title 6. However, "subagent" does not include an associate licensee who is acting under the supervision of an agent in a real property transaction.

2079.14. Listing agents and selling agents shall provide the seller and buyer in a real property transaction with a copy of the disclosure form specified in Section 2079.16, and, except as provided in subdivision (c), shall obtain a signed acknowledgment of receipt from that seller or buyer, except as provided in this section or Section 2079.15, as follows:

(a) The listing agent, if any, shall provide the disclosure form to the seller prior to entering into the listing agreement.

(b) The selling agent shall provide the disclosure form to the seller as soon as practicable prior to presenting the seller with an offer to purchase, unless the selling agent previously provided the seller with a copy of the disclosure form pursuant to subdivision.

(c) Where the selling agent does not deal on a face-to-face basis with the seller, the disclosure form prepared by the selling agent may be furnished to the seller (and acknowledgment of receipt obtained for the selling agent from the seller) by the listing agent, or the selling agent may deliver the disclosure form by certified mail addressed to the seller at his or her last known address, in which case no signed acknowledgment of receipt is required.

(d) The selling agent shall provide the disclosure form to the buyer as soon as practicable prior to execution of the buyer's offer to purchase, except that if the offer to purchase is not prepared by the selling agent, the selling agent shall present the disclosure form to the buyer not later than the next business day after the selling agent receives the offer to purchase from the buyer.

2079.15. In any circumstance in which the seller or buyer refuses to sign an acknowledgment of receipt pursuant to Section 2079.14, the agent, or an associate licensee acting for an agent, shall set forth, sign, and date a written declaration of the facts of the refusal.

2079 17.

(a) As soon as practicable, the selling agent shall disclose to the buyer and seller whether the selling agent is acting in the real property transaction exclusively as the buyer's agent, exclusively as the seller's agent, or as a dual agent representing both the buyer and the seller. This relationship shall be confirmed in the contract to purchase and sell real property or in a separate writing executed or acknowledged by the seller, the buyer, and the selling agent prior to or coincident with execution of that contract by the buyer and the seller, respectively.

(b) As soon as practicable, the listing agent shall disclose to the seller whether the listing agent is acting in the real property transaction exclusively as the seller's agent, or as a dual agent representing both the buyer and seller. This relationship shall be confirmed in the contract to purchase and sell real property or in a separate writing executed or acknowledged by the seller and the listing agent prior to or coincident with the execution of that contract by the seller.

(c) The confirmation required by subdivisions (a) and (b) shall be in the following form:

_____is the Listing agent of (check one): ( ) the seller exclusively; or ( ) both the buyer and seller.
_____is the Selling agent, *if not the same as the Listing Agent* , of (check one): ( ) the buyer exclusively; or ( ) the seller exclusively; or ( ) both the buyer and seller.

(d) The disclosures and confirmation required by this section shall be in addition to the disclosure required by Section 2079.14.

2079.18. No selling agent in a reed property transaction may act as an agent for the buyer only, when the selling agent is also acting as the listing agent in the transaction.

2079.19. The payment or compensation or the obligation to pay compensation to an agent by the seller or buyer is not necessarily determinative of a particular agency relationship between an agent end the seller or buyer. A listing agent and a selling agent may agree to share any compensation or commission paid, or any right in any compensation or commission for which an obligation arises as the result of a real estate transaction, and the terms of any such agreement shag not necessarily be determinative of a particular relationship.

2079.20. Nothing in this article prevents an agent from selecting, as a condition of the agent's employment, a specific form of agency relationship not specifically prohibited by this article if the requirements of Section 2079.14 and Section 2079.17 are complied with.

2079.21. A dual agent shall not disclose to the buyer that the seller is willing to sell the property at a price less than the listing price, without the express written consent of the seller. A dual agent shall not disclose to the seller that the buyer is willing to pay a price greater than the offering price, without the express written consent of the buyer. This section does not alter in any way the duty or responsibility of a dual agent to any principal with respect to confidential information other than price

2079.22. Nothing in this article precludes a listing agent from also being a selling agent, and the combination of these functions in one agent clues not, of itself, make that agent a duel agent.

2079.23. A contract between the principal and agent may be modified or altered to change the agency relationship at any time before the performance of the act which is the object of the agency with the written consent of the parties to the agency relationship.

2079.24. Nothing in this article shall be construed to either diminish the duty of disclosure owed buyers and sellers by agents and their associate licensees, subagents, and employees or to relieve agents and their associate licensees, subagents, and employees from liability for their conduct in connection with acts governed by this ankle or for any breach of a fiduciary duty or a duty of disclosure.

Exhibit 21

Subsidiaries

Subsidiary Name	Jurisdiction
Glaukos Europe GmbH	Germany
Glaukos Japan GK	Japan
Glaukos Australia Pty Ltd	Australia
Glaukos Canada Inc.	Canada

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-205372) pertaining to Glaukos Corporation 2015 Omnibus Incentive Compensation Plan, 2015 Employee Stock Purchase Plan, 2011 Stock Plan, and 2001 Stock Option Plan of our report dated March 14 , 2016, with respect to the consolidated financial statements of Glaukos Corporation included in this Annual Report (Form 10-K) for the year ended December 31, 2015, filed with the Securities and Exchange Commission.

/s/ Ernst & Young LLP

Irvine, California
March 14 , 2016

Exhibit 31.1

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

I, Thomas W. Burns, certify that:

1. I have reviewed this Annual Report on Form 10-K of Glaukos Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15(d)-15(e)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 1 4 , 2016

/s/ Thomas W. Burns
Thomas W. Burns
President and Chief Executive Officer

Exhibit 31.2

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

I, Richard L. Harrison, certify that:

1. I have reviewed this Annual Report on Form 10-K of Glaukos Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15(d)-15(e)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 1 4 , 2016

/s/ Richard L. Harrison

Richard L. Harrison

Treasurer, Chief Financial Officer and Secretary

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Thomas W. Burns, President and Chief Executive Officer of Glaukos Corporation (the "Company"), certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

(i) the Annual Report on Form 10-K of the Company for the year ended December 31, 2015 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 1 4 , 2016

/s/ Thomas W. Burns

Thomas W. Burns

President and Chief Executive Officer

This certification is being "furnished" with this Report, shall not be deemed "filed" by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability under that Section and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Report, irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

I, Richard L. Harrison, Chief Financial Officer of Glaukos Corporation (the "Company"), certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

(i) the Annual Report on Form 10-K of the Company for the year ended December 31, 2015 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 1 4 , 2016

/s/ Richard L. Harrison

Richard L. Harrison

Treasurer, Chief Financial Officer and Secretary

This certification is being "furnished" with this Report, shall not be deemed "filed" by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability under that Section and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Report, irrespective of any general incorporation language contained in such filing.