IRIDEX CORP
Form 10-K
March 29, 2019

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 SECURITY EXCHANGE ACT OF 1934
For the fiscal year ended December 29, 2018

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITY EXCHANGE ACT OF 1934
For the transition period from to .

Commission File Number 0-27598

IRIDEX CORPORATION

(Exact name of Registrant as specified in its charter)

Delaware	77-0210467
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1212 Terra Bella Avenue	(650) 940-4700	94043
Mountain View, CA	(Registrant’s telephone number, including area code)	(Zip Code)
(Address of principal executive offices)		

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

Title of Each Class	Name of Each Exchange on Which Registered
Common	Nasdaq Global Market

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

Common Stock, par value $0.01 per share

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act of 1933. Yes No

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 (the "Exchange 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 Exchange Act during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (Section 229.405 of this chapter) is not contained herein, and will not be contained, to the best of 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, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definition of "large accelerated filer", "accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.:

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

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

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

The aggregate market value of the voting common equity held by non-affiliates of the Registrant was approximately $40,449,599 as of June 29, 2018, the last business day of the Registrant's most recently completed second fiscal quarter, based on the closing price reported for such date on the Nasdaq Global Market. The registrant did not have any non-voting common equity outstanding. For purposes of this disclosure, shares of common stock held by each

executive officer and director and by each holder of 5% or more of the outstanding shares of common stock have been excluded from this calculation, because such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 14, 2019, Registrant had 13,632,797 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain parts of the Proxy Statement for the Registrant's 2019 Annual Meeting of Stockholders (the "Proxy Statement") are incorporated by reference into Part III of this Annual Report on Form 10-K.

USE OF FORWARD-LOOKING STATEMENTS

In this document, we refer to Iridex Corporation and its subsidiaries (unless the context otherwise requires) as “we,” the “Company” or “Iridex.” With the exception of historical information contained in this Annual Report on Form 10-K, content herein may contain “forward looking statements” that are made pursuant to the Safe Harbor Provisions of the Private Securities Litigation Reform Act of 1995. These statements are based on management’s current expectations and are subject to uncertainty and changes in circumstances. We cannot guarantee that any forward-looking statements will be accurate, although we believe that we have been reasonable in our expectations and assumptions. Investors should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from our expectations and projections. These factors include general economic conditions, delays and risks associated with the performance of contracts, risks associated with international sales and currency fluctuations, uncertainties as a result of research and development, acceptable results from clinical studies, including publication of results and patient/procedure data with varying levels of statistical relevance, risks involved in introducing and marketing new products, regulatory compliance, potential acquisitions, consumer and industry acceptance, litigation and/or contemplated 510(k) filings, the ability to achieve and maintain profitability in our business lines, and other factors discussed in this Annual Report on Form 10-K, subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. We disclaim any obligation to update any forward-looking statements.

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PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains certain 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. These statements are based on management's beliefs and assumptions and on information currently available to management. These statements include statements concerning future demand and order levels for the Company's products, future operating expenses, changes in personnel, product development and intellectual property related matters, the adoption and effect of Company products on its results, the markets in which the Company operates, usage and efficacy of the Company's products, the Company's future financial results, and the Company's strategic plans and objectives. In some cases, forward-looking statements can be identified by terminology, such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "intends," "potential," "continue," or the negative of such terms or other comparable terminology, although not all forward looking statements contain these words.

These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to differ materially from those expressed or implied by such forward-looking statements. The reader is strongly urged to read the information contained under the captions "Item 1A. Risk Factors - Factors That May Affect Future Results" in this Annual Report on Form 10-K for a more detailed description of these significant risks and uncertainties. The reader is cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this Annual Report on Form 10-K. We undertake no obligation to update such forward-looking statements to reflect events or circumstances occurring after the date of this report.

As used in this Annual Report on Form 10-K, the terms "Company," "IRIDEX," "we," "us" and "our" refer to IRIDEX Corporation, and its consolidated subsidiaries.

Item 1. Business

Overview

IRIDEX Corporation is an ophthalmic medical technology company focused on the development and commercialization of breakthrough products and procedures used to treat sight-threatening eye conditions, including glaucoma and retinal diseases. Certain of our laser products are powered by our proprietary MicroPulse technology, which is a method of delivering laser energy using a mode which chops the continuous wave laser beam into short, microsecond-long laser pulses. Our products consist of laser consoles, delivery devices and consumable instrumentation, including laser probes.

Our laser consoles consist of the following product lines:

- Glaucoma – This product line includes our Cyclo G6 laser system used for the treatment of glaucoma;
- Medical Retina – Our medical retina product line includes our IQ 532 and IQ 577 laser photocoagulation systems, which are used for the treatment of diabetic macular edema and other retinal diseases; and
- Surgical Retina – Our surgical retina line of products includes our OcuLight TX, OcuLight SL, OcuLight SLx, OcuLight GL and OcuLight GLx laser photocoagulation systems. These systems are often used in vitrectomy procedures, which are used to treat proliferative diabetic retinopathy, macular holes, retinal tears and detachments.

Our business generates recurring revenues through sales of consumable products, predominantly single-use laser probe devices and other instrumentation, as well as repair, servicing and extended service contracts for our laser systems. Our laser probes consist of the following product lines:

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- Glaucoma – Probes used in our glaucoma product line include our patented MicroPulse P3 (“MP3”) probe and G-Probe; and
- Surgical Retina – Our surgical retina probes include our EndoProbe family of products used in vitrectomy procedures.

Ophthalmologists typically use our laser systems in hospital operating rooms (“ORs”) and ambulatory surgical centers (“ASCs”), as well as their offices and clinics. In the ORs and ASCs, ophthalmologists use our laser systems with either an indirect laser ophthalmoscope or a consumable, single use MP3 probe, G-Probe or EndoProbe.

Our products are sold in the United States and Germany predominantly through a direct sales force and internationally primarily through independent distributors. In 2017, we established direct sales capabilities in Germany. Total revenues in 2018 and 2017 were $42.6 million and $41.6 million, respectively. We generated net losses of $12.8 million and $12.9 million in 2018 and 2017, respectively.

IRIDEX Corporation was incorporated in California in February 1989 as IRIS Medical Instruments, Inc. In January 1996, we changed our name to IRIDEX Corporation and reincorporated in Delaware. Our executive offices are located at 1212 Terra Bella Avenue, Mountain View, California 94043-1824, and our telephone number is (650) 940-4700. We can also be reached at our website at www.IRIDEX.com, however, the information on, or that can be accessed through, our website is not part of this report.

Our Market Opportunity

Ophthalmology is a large and growing global market that is driven by the aging world population and the onset of chronic diseases. We currently target the glaucoma and retina disease markets.

Glaucoma

Glaucoma is a leading cause of blindness in the world. Glaucoma is a progressive, chronic disease and vision loss resulting from glaucoma currently cannot be regained. According to Market Scope, more than 80 million people worldwide have glaucoma, while only about 30% of those patients have been diagnosed as having it. Glaucoma is most commonly associated with elevated levels of pressure within the eye, or intraocular pressure (“IOP”). Elevated IOP often occurs when aqueous humor, the thin watery fluid that fills the front of the eye, is not circulating normally and draining properly. Currently, reducing IOP is the only proven treatment for glaucoma with treatments primarily focused on improving the flow of aqueous humor through the eye’s trabecular meshwork and uveoscleral outflow pathways. Global sales of products used to diagnose and treat glaucoma are expected to total $5.8 billion in 2018, according to Market Scope’s 2018 Global Glaucoma Surgical Device Market.

Pharmaceutical products represent a majority of this revenue estimate but have significant shortcomings. Pharmaceuticals are typically the first treatment method prescribed for glaucoma. These pharmaceutical treatments are commonly self-administered in drop form by the patients. Patients often have difficulties applying the pharmaceutical drops properly and may fail to appropriately or timely apply the medication, which may significantly reduce the effectiveness of the pharmaceutical. This 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 when administered correctly, pharmaceuticals have demonstrated reduced efficacy over time.

When pharmaceuticals lose their effectiveness, appropriate treatment options are determined based on the progression and severity of the disease and include traditional laser therapy (e.g. selective laser trabeculoplasty (“SLT”), minimally invasive stents/shunts (e.g. MIGS), and open surgery (e.g. trabeculectomy)). These treatment alternatives also have significant shortcomings due to treatment effects that dissipate over time, repeat procedures that are less effective or not clinically advised, limited indications of use, and significant complication risks.

We believe that because of the limitations of these traditional treatment alternatives, a clear unmet medical need exists in the management of glaucoma patients.

Medical Retina

Per Market Scope estimates in 2016, global sales of retinal surgical products will increase to $2.7 billion in 2021. Our medical retina business focuses on the treatment of diabetic macular edema (“DME”) which is part of a broader disease state called diabetic retinopathy. Diabetic retinopathy is a common complication of diabetes which impairs vision over

time and, if left untreated, can lead to blindness. An estimated 285 million people worldwide had diabetes in 2010, according to the International Diabetes Federation. The federation predicts as many as 438 million will have diabetes globally by 2030. Previous clinical publications, such as an article cited at the U.S. National Institutes of Health's National Library of Medicine, indicated 28.5% of diabetic patients can develop some form of diabetic retinopathy. Traditional laser photocoagulation and a regimen of injected pharmaceuticals are currently the standard treatment for this disease and are associated with significant shortcomings. Traditional laser photocoagulation can stabilize the patient's vision over the long term but presents a risk of varying degrees of vision loss to the patient. Pharmaceuticals can stabilize vision in the near term but require repeated injections. The injections are painful and the patients may experience side effects including increased risk of eye infections. Furthermore, a regimen of repeated pharmaceutical injections is very costly to the physician and patient, in terms of time, and to the healthcare system, in terms of dollars spent on treatment.

The shortcomings in treating retinal diseases have led to a renewed interest in alternative approaches that may provide better or comparable patient outcomes at lower costs.

Our Solution

Our traditional laser technology was developed to perform laser photocoagulation by using a mode that delivers continuously-on laser light, which is referred to as continuous wave ("CW") mode. Laser photocoagulation generates a local healing response and has been demonstrated to be a safe and effective therapy with long-term benefits for certain ophthalmic procedures. However, use of the CW mode typically leads to local tissue damage and can cause loss of visual function, which limits the applications of the technology.

We developed our proprietary MicroPulse technology with the goal of harnessing the clinical benefits of CW mode while minimizing the associated tissue damage. MicroPulse is a method of delivering laser energy using a mode which chops the CW beam into short, microsecond long laser pulses. The laser pulses are intended to generate the desired therapeutic response while the time in between laser pulses is believed to enable the tissue to cool and thereby minimize tissue damage. This is analogous to holding one's hand continuously over a candle versus waving it back and forth. When held continuously, the candle would cause burning and scar tissue. However, when exposed intermittently the candle only heats the tissue without burning.

There is a growing body of clinical evidence that has been published over the past 10 years that demonstrates that MicroPulse therapy is clinically effective with limited tissue damage for the treatment of glaucoma and retinal diseases. Currently, we have developed three applications of our MicroPulse technology for the treatment of eye diseases:

MicroPulse Applications	Description
Glaucoma – uveoscleral outflow	Treats glaucoma with our Cyclo G6 laser system. MicroPulse laser is delivered through a proprietary single-use disposable probe we call the MicroPulse P3 (MP3) probe. By targeting an anatomical area of the eye called "Pars Plana" it is believed that the MP3 procedure may improve uveoscleral outflow and thus lower IOP and may reduce the number of eye drop medications. The MP3 procedure has the potential to be used across a wide spectrum of glaucoma disease severity, given its believed therapeutics benefits and non-incisional approach with minimal tissue damage and complications. We believe that the MP3 procedure has several important competitive advantages over alternative therapies with respect to invasiveness, sustained IOP reduction and does not inhibit the physicians from the use of alternative procedures.
Glaucoma - trabecular meshwork outflow	Treats glaucoma with our IQ laser systems. MicroPulse laser is delivered through a mechanical and optical delivery device and targets the trabecular meshwork. Physicians describe the technique as MicroPulse Laser Trabeculoplasty ("MLT"). It is believed that the MLT procedure improves trabecular meshwork outflow and thus lowers IOP. We believe that the MLT procedure provides incremental clinical benefits relative to other laser trabeculoplasty procedures such as SLT.
Medical Retina - DME	Treats DME with our IQ laser systems. MicroPulse laser is administered through a mechanical and optical delivery device that rapidly delivers multiple treatment spots on the retina. Our MicroPulse laser is uniquely believed to be "fovea friendly" in that the laser can be used to treat the fovea, the center of the field of vision in the retina, without any loss of visual function. Instead of causing thermal damage like traditional lasers, MicroPulse is believed to induce a therapeutic response through the recruitment of biological factors such as heat shock proteins. We believe that the treatment of DME with MicroPulse has several competitive advantages over alternate therapies with respect to long term vision stability, visual function, and cost effectiveness.

Our Strategy

We are one of the worldwide leaders in developing, manufacturing, marketing, selling and servicing innovative medical laser systems and associated instrumentation for the treatment of sight-threatening eye diseases. Our strategy is to leverage our existing brand and distribution channel in the ophthalmology market to promote the adoption of MicroPulse as a viable treatment alternative for glaucoma and retinal diseases and consequently to commercialize a broad array of products that:

- Improve therapeutic outcomes for patients suffering from sight-threatening eye diseases;
- Improve the efficiency of physicians and reduce their costs; and
- Provide economic benefits to healthcare systems.

To achieve these goals, we are pursuing a number of organic initiatives that we anticipate will be supplemented from time to time by acquisitions. We anticipate that the successful execution of this strategy will lead to profitable growth and enhanced shareholder value.

Our Products

Our current product portfolio utilizes a system approach. Each system includes a laser console, which generates the laser energy, and a number of interchangeable delivery devices or disposable probes for use in specific clinical applications. This approach allows our customers to purchase a basic laser system and add additional delivery devices or disposable probes as their therapeutic needs expand or as new applications develop. We currently offer three basic product categories: 1) laser consoles, 2) delivery devices which are optical-mechanical products that mount to ophthalmologists diagnostic equipment and transmit the laser and 3) single-use disposable probes that transmit the laser light to a targeted region within the inside of an eye.

Laser Consoles

Our laser consoles, which are identified below, incorporate the economic and technical benefits of solid state and semiconductor laser technology.

Glaucoma: Cyclo G6 Laser System. The Cyclo G6 is an infrared (810nm) laser designed to treat patients diagnosed with a range of glaucoma disease states. The Cyclo G6 system is sold with a family of probes that are disposable, including our patented MP3 probe that utilizes our MicroPulse technology and our G-Probe.

Medical retina: IQ laser systems. Our IQ laser systems offer our MicroPulse technology but also have CW capabilities. Our IQ 577 delivers visible yellow (577nm) laser light and our IQ 532 delivers visible green (532nm) laser light. Our IQ laser systems are typically used with our TxCell Scanning Laser Delivery System and our Slit Lamp Adapters when used to treat DME with MicroPulse.

Surgical retina: OcuLight laser systems. Our OcuLight TX, OcuLight GL, and OcuLightGLx lasers deliver visible green (532nm) laser light. Our OcuLight SL and OcuLightSLx lasers deliver infrared (810 nm) laser light.

Delivery Devices

The following delivery devices are typically used with our IQ and OcuLight laser systems:

TxCell Scanning Laser Delivery System (“TxCell”). TxCell allows the physician to perform multi-spot pattern scanning for efficient delivery of our MicroPulse laser.

Slit Lamp Adapter (“SLA”). These adapters allow the physician to utilize a standard slit lamp in both diagnosis and treatment procedures. Physicians can install an SLA in a few minutes and convert standard diagnostic slit lamps into a

therapeutic laser delivery system. SLAs are used in treatment procedures for both retinal diseases and glaucoma.

Laser Indirect Ophthalmoscope (“LIO”). The indirect ophthalmoscope is designed to be worn on the physician’s head and to be used in procedures to treat peripheral retinal disorders, particularly in infants or adults requiring treatment in the supine position. This product can be used in both diagnosis and treatment procedures at the point-of-care.

Single-use disposable probes

MicroPulse P3 Probe. The MP3 Probe is used with our Cylco G6 laser systems and is our probe that delivers our MicroPulse laser to treat glaucoma. It is believed that the MP3 procedure reduces IOP through a multi-factorial mechanism of action - it perhaps improves outflow through natural drainage pathways such as the uveoscleral and the trabecular meshwork while also reducing certain inflow. The MP3 Probe can be performed on an anesthetized eye in the doctor’s office or OR. The non-incisional procedure takes just a few minutes and results in minimal post-operative recovery for the patient. We believe that the MP3 procedure may be used to treat a wide variety of glaucoma states, including early to late stage glaucoma as well as open-angle and closed angle glaucoma. The MP3 Probe is a sterile disposable product.

G-Probe. The G-Probe is used in procedures to treat uncontrolled glaucoma, typically described as “refractory glaucoma”. The G-Probe delivers CW laser to the ciliary body and is believed to stop the production of aqueous humor, thus reducing IOP. The G-Probe’s non-invasive procedure takes approximately ten minutes and is performed on an anesthetized eye in the doctor’s office or OR. The G-Probe is a sterile disposable product.

G-Probe Illuminate. The G-Probe Illuminate is also used in procedures to treat refractory glaucoma. The proprietary illumination feature allows for more targeted treatment and may offer additional clinical benefits. The G-Probe Illuminate is a sterile disposable product.

EndoProbe. Our EndoProbe family of products are used for endophotocoagulation, a retinal treatment procedure performed in the hospital OR or surgery center during a vitrectomy procedure. Vitrectomy procedures are performed to treat proliferative diabetic retinopathy, macular holes, retinal tears and detachments. These disposable probes are available in tapered, angled, stepped, aspirating, illuminating, and adjustable styles, as well as a wide variety of sizes. The EndoProbe is a sterile disposable product.

Research and Development

We have close working relationships with researchers, clinicians and practicing physicians around the world who provide new ideas, evaluate prototypes and assist us in validating new products and new applications before they are introduced.

Our internal research and development (“R&D”) activities are performed by a current team of 11 engineers and regulatory professionals with experience in various aspects of medical products, laser systems, delivery devices, clinical techniques, and regulatory affairs with a focus on introducing innovative products which satisfy the unmet and emerging needs of our customers. The core competencies of the team include: mechanical engineering, electrical engineering, optics, lasers, fiber optics, software, and industrial designs. The R&D process integrates all necessary disciplines of the Company from product inception through customer acceptance. This process facilitates reliable new product innovations and a consistent pipeline of innovative products for our customers.

Our research activities are managed internally by our R&D staff. We supplement our internal R&D staff by hiring consultants or partnering with physicians known for their expertise. Research efforts are directed toward the development of new products, as well as the identification of markets not currently addressed by our products.

We believe that it is important to make a substantial contribution to improving clinical outcomes. For instance, we have made substantial investments in improving the treatment of serious eye diseases such as glaucoma and retinal disease. The objectives of developing new treatments and applications are to expand the patient population, to better and more economically treat diseases, to treat patients earlier in the treatment regimen and to reduce the side effects of treatment.

We consider clinical projects to be a component of our R&D efforts and they may or may not result in additional commercial opportunities.

Customers and Customer Support

Our products are currently sold for use by ophthalmologists specializing in the treatment of eye disease in retina, glaucoma and pediatric eye diseases. Other customers include research and teaching hospitals, government installations, surgical centers, hospitals, and office clinics (outpatient). No single customer or distributor accounted for 10% or more of total revenues in fiscal years 2018 and 2017.

We seek to provide superior customer support and service and believe that our customer service and technical support distinguish our product offerings from those of our competitors. We provide depot service at our Mountain View

facility for our products. Our customer support representatives assist customers with orders, warranty returns and other administrative functions. Our technical support engineers provide customers with answers to technical and product-related questions. We maintain an “around-the-clock” telephone service line to service our customers. If a problem with a depot serviceable product cannot be diagnosed and resolved by telephone, a service loaner is shipped overnight to domestic customers under warranty or service contract, and by the most rapid delivery means available to our international customers, and the problem unit is returned to us. The small size and rugged design of our products allows for economical shipment and quick response to customers worldwide.

Sales and Marketing

We sell and market our products in the United States and Germany predominantly through our direct sales force and internationally through independent distributors. Currently we have a direct sales force of 20 employees who are engaged in sales efforts within the United States, 3 in Germany and 6 personnel engaged in managing our distribution sales efforts internationally. Our sales are administered through our corporate headquarters in Mountain View, California.

International revenues represented 48.1% and 44.7% of our revenues in 2018 and 2017, respectively. We believe that our international sales will continue to represent a significant portion of our revenues for the foreseeable future. Our international sales are made principally to customers in Europe, Asia, the Pacific Rim, the Middle East, Russia, Africa and Latin America. Our distribution agreements with our international distributors are generally exclusive and typically can be terminated by either party without cause with 90 days' notice. International sales may be adversely affected by currency fluctuations, the imposition of governmental controls, restrictions on export technology, political instability, trade restrictions, changes in tariffs and the economic condition in each country in which we sell our products.

To support our sales process, we conduct marketing programs which include: our website, clinical education, social media, email marketing, trade shows, public relations, market research, key opinion leader collaborations and advertising in trade and academic journals and newsletters. We typically participate in over 85 trade shows worldwide on an annual basis. These meetings allow us to present our products to existing and prospective buyers.

Through marketing, we collaborate with our customers to identify new products and applications which help meet their needs, and in turn provides us with new product concepts, enhances our ability to identify new applications for our products and validates new procedures using our products. Customers include key opinion leaders who are often the heads of the departments in which they work or professors at universities. We believe that these luminaries in the field of ophthalmology are key to the successful introduction of new products and the subsequent acceptance of these new products by the general market. Acceptance of our products by these early adopters is key to our strategy in the validation and commercialization of our new products.

Clinical Affairs

Our clinical affairs group was established to support clinical research opportunities, provide specialized ophthalmic surgeon training and credentialing for our proprietary MicroPulse™ products, establish strong relationships with prominent key opinion leaders and assure the accuracy and consistency our messaging to the market. We believe that a strong research program underlying marketing initiatives and professional level training for our customers are key to driving the application of our technology for more widespread and consistent use.

Operations

The manufacture of our visible light and infrared laser consoles and the related delivery devices is a highly complex and precise process. Completed systems must pass quality control and reliability tests before shipment. Our manufacturing activities consist of specifying, sourcing, assembling and testing of components and certain subassemblies for assembly into our final product. Currently we have a total of 17 employees engaged in manufacturing activities for these products.

The medical devices we manufacture are subject to extensive regulation by numerous governmental authorities, including federal, state, and foreign governmental agencies. The principal regulators in the United States are the Food and Drug Administration ("FDA") and the California Department of Public Health, Food and Drug Branch. In April 1998, we received certification for ISO 9001/EN 46001, which is an international quality system standard that documents compliance to the European Medical Device Directives. In February 2004, we were certified to ISO 13485:2003, which replaced ISO 9001/EN46001 as the international standard for quality systems as applied to medical devices. In December 2018, we were certified to ISO 13485:2016, which superseded the 2003 version of the standard. In August 2008, we received FDA 510(k) clearance on our family of IRIDEX IQ laser systems. This clearance covers the IRIDEX IQ 532 and IQ 577 laser systems and their associated delivery devices to deliver laser energy in either CW or MicroPulse mode. In January 2015, we received FDA 510(k) clearance for Cyclo G6. These laser systems are intended for a wide range of specific applications in the medical specialties of ophthalmology.

International regulatory bodies often establish varying product standards, packaging requirements, labeling requirements, tariff regulations, duties and tax requirements. As a result of our sales in Europe, we are required to have all products “CE” marked, an international symbol affixed to all products demonstrating compliance to the European Medical Device Directives and all applicable standards. In July 1998, we received CE mark certification under Annex II guidelines, the most stringent path to CE certification. With Annex II CE mark certification, we have demonstrated our ability to both understand and comply with all applicable standards under the European Medical Device Directives. Currently, all of our released products are CE marked. Continued certification is based on successful review of the process by our European Registrar during its annual audit. Any loss of certification would have a material adverse effect on our business, results of operations and financial condition. We rely on third parties to manufacture substantially all of the components used in our products, although we assemble critical subassemblies and the final product at our facility in Mountain View, California. Some of these suppliers and manufacturers are sole source. We have some long-term or volume purchase agreements with our suppliers but currently purchase most components on a purchase order basis. These components may not be available in the quantities required, on reasonable terms, or at all. Financial or other difficulties faced by our suppliers or significant changes in demand for these components or materials could limit their availability. Any failures by our third-party suppliers to adequately perform may delay the submission of products for regulatory approval, impair our ability to deliver products on a timely basis or otherwise impair our competitive position.

Competition

Competition in the market for laser systems and delivery devices used for ophthalmic treatment procedures is intense and is expected to increase. This market is also characterized by technological innovation and change. We compete by providing features and services that are valued by our customers such as: enhanced product performance, and clinical outcomes, ease of use, durability, versatility, customer training services and rapid repair of equipment.

Our principal ophthalmic laser competitors are Alcon Inc. (Novartis AG), Bausch and Lomb (Valeant), Carl Zeiss Meditec AG, Ellex Medical Lasers, Ltd., Lumenis Ltd., Nidek Co. Ltd., Quantel Medical SA, and Topcon Corporation. We also compete with alternative glaucoma surgical device companies such as Alcon, Allergan, Glaukos, New World Medical and Ivantis. Pharmaceuticals represent alternative treatments to our laser procedures. Some of our principal pharmaceutical competitors are Alcon, Allergan, OSI Pharmaceuticals, Pfizer, Regeneron, Roche (Genentech), and Valeant Pharmaceuticals. Some of our competitors have substantially greater financial, engineering, product development, manufacturing, marketing and technical resources than we do. Some companies also have greater name recognition than us and long-standing customer relationships. In addition, other medical companies, academic and research institutions, or others, may develop new technologies or therapies, including medical devices, surgical procedures or pharmacological treatments and obtain regulatory approval for products utilizing such techniques that are more effective in treating the conditions targeted by us, or are less expensive than our current or future products. Our technologies and products could be rendered obsolete by such developments. Any such developments could have a material adverse effect on our business, financial condition and results of operations.

Patents and Proprietary Rights

Our success and ability to compete is dependent in part upon our proprietary information. We rely on a combination of patents, trade secrets, copyright and trademark laws, nondisclosure and other contractual agreements and technical measures to protect our intellectual property rights. These are either developed internally or obtained from acquisitions such as RetinaLabs and Ocunetics. We file patent applications to protect technology, inventions and improvements that are significant to the development of our business. Our patent portfolio includes 20 active United States patents and 13 active foreign patents on the technologies related to our products and processes. In addition, we have 8 patent applications pending in the United States and 12 foreign patent applications pending. Our patent applications may not be approved.

In addition to patents, we rely on trade secrets and proprietary know-how which we seek to protect, in part, through proprietary information agreements with employees, consultants and other parties. Our proprietary information agreements with our employees and consultants contain provisions requiring such individuals to assign to us, without additional consideration, any inventions conceived or reduced to practice by them while employed or retained by us, subject to customary exceptions.

Government Regulation

The medical devices marketed and manufactured by us are subject to extensive regulation by numerous governmental authorities, including federal, state, and foreign governmental agencies. Pursuant to the Federal Food, Drug, and Cosmetic Act (“FD&C Act”), as amended, and the regulations promulgated thereunder, the FDA serves as the principal federal agency within the United States with authority over medical devices and regulates the research, clinical testing, manufacture, labeling, distribution, sale, marketing and promotion of such devices. Noncompliance with applicable requirements can result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizures of products, total or partial suspension of production, failure of the government to grant pre-market clearance or approval for devices, withdrawal of marketing approvals, and criminal prosecution. The FDA also has the authority to request repair, replacement or refund of the cost of any medical device manufactured or distributed by us.

In the United States, medical devices are classified into one of three classes - Class I, II or III. The class to which the device is assigned determines, among other things, the type of pre-marketing submission/application required for FDA clearance to market. If the device is classified as Class I or II, and if it is not exempt, a 510(k) pre-market notification will be required for marketing. Under FDA regulations, Class I devices are subject to general controls (for example, labeling, pre-market notification and adherence to Quality System Regulations ("QSRs") requirements). Class II devices receive marketing clearance through a 510(k) pre-market notification. For Class III devices, a pre-market approval ("PMA") application will be required unless the device is a pre-amendments device (on the market prior to the passage of the medical device amendments in 1976, or substantially equivalent to such a device) and PMAs have not been called for. In that case, a 510(k) will be the route to market. A 510(k) clearance will be granted if the submitted information establishes that the proposed device is substantially equivalent to a legally marketed Class I or II medical device, or to a Class III medical device for which the FDA has not called for a PMA. The FDA may determine that a proposed device is not substantially equivalent to a legally marketed device or that additional information or data are needed before a substantial equivalence determination can be made. A request for additional data may require that clinical studies of the device's safety and efficacy be performed.

Commercial distribution of a device for which a 510(k) notification is required can begin only after the FDA issues an order finding the device to be substantially equivalent to a previously cleared device. The FDA has recently been requiring a more rigorous demonstration of substantial equivalence than in the past. Even in cases where the FDA grants a 510(k) clearance, it can take the FDA between three and six months from the date of submission to grant a 510(k) clearance, but it may take longer.

A “not substantially equivalent” (NSE) determination, or a request for additional information, could delay the market introduction of new products that fall into this category and could have a materially adverse effect on our business, financial condition and results of operations. For any of our products that are cleared through the 510(k) process, modifications or enhancements that could significantly affect the safety or efficacy of the device or that constitute a major change to the intended use of the device will require new 510(k) submissions.

We have obtained 510(k) clearances for all of our marketed products. We have also modified aspects of our products since receiving regulatory clearance, and we have submitted 510(k)s for those modifications as required by FDA regulations. After a device receives a 510(k) clearance or a PMA, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new clearance or approval. 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 our determination not to seek a new 510(k) clearance or PMA, the FDA may retroactively require us to seek 510(k) clearance or pre-market approval. The FDA could also require us to cease marketing and distribution and/or recall the modified device until a 510(k) clearance or a PMA approval is obtained. Also, in these circumstances, we may be subject to significant regulatory fines or penalties.

Any products manufactured or distributed by us pursuant to FDA clearances or approvals are subject to pervasive and continuing regulation by the FDA, including record keeping requirements and reporting of adverse experiences with the use of the device. Device manufacturers are required to register their establishments and list their devices with the FDA and certain state agencies, and are subject to periodic inspections by the FDA and certain state agencies. The FD&C Act requires devices to be manufactured to comply with applicable QSR regulations which impose certain procedural and documentation requirements upon us with respect to design, development, manufacturing and quality assurance activities. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of the California Department of Public Health, to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our subcontractors.

Labeling and promotion activities are subject to scrutiny by the FDA and in certain instances, by the Federal Trade Commission. The FDA actively enforces regulations prohibiting marketing of products for unapproved uses. We and our products are also subject to a variety of state laws and regulations in those states or localities where our products are or will be marketed. Any applicable state or local regulations may hinder our ability to market our products in those states or localities. Manufacturers are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. We may be required to incur significant costs to comply with such laws and regulations now or in the future. Such laws or regulations may have a material adverse effect upon our ability to do business.

Export of our products is regulated by the FDA and subject to the FD&C Act, 21 U.S.C. §§321-397, and other statutes FDA administers, which greatly expanded the export of approved and unapproved United States medical devices. However, some foreign countries require manufacturers to provide a specific type of FDA export certificate (such as a Certificate to Foreign Government or Certificate of Exportability) which requires the device manufacturer to certify to the FDA that the product has been granted pre-market clearance in the United States and that the manufacturing facilities appeared to be in compliance with QSR at the time of the last QSR inspection. The FDA will refuse to issue any export certificate if significant outstanding QSR violations exist.

We are also regulated under the Radiation Control provisions (originally enacted as the Radiation Control for Health and Safety Act of 1968) which are located in Sections 531 through 542 of the FD&C Act, which requires laser products to comply with performance standards, including design and operation requirements, and manufacturers to certify in product labeling and in reports to the FDA that their products comply with all such standards. The law also requires laser manufacturers to file new product and annual reports, maintain manufacturing, testing and sales records and report product defects. Various warning labels must be affixed and certain protective devices installed, depending on the class of the product.

The introduction of our products in foreign markets will also subject us to foreign regulatory clearances which may impose substantial additional costs and burdens. International sales of medical devices are subject to the regulatory requirements of each country. The regulatory review process varies from country to country. Many countries also impose product standards, packaging requirements, labeling requirements and import restrictions on devices. In addition, each country has its own tariff regulations, duties and tax requirements. The approval by the FDA and foreign government

authorities is unpredictable and uncertain. The necessary approvals or clearances may not be granted on a timely basis, if at all. Delays in receipt of, or a failure to receive, such approvals or clearances, or the loss of any previously received approvals or clearances, could have a material adverse effect on our business, financial condition and results of operations. There are a number of major regulatory changes occurring in the regulation of medical devices in the European Union. A new revision of the quality system regulation (ISO 13485:2016) has been released that substantially increases the requirements for a medical device quality system. The Medical Device Regulation ("MDR") will replace the current medical device directives (93/42/EEC), and it substantially changes the way that medical devices are brought to market in the European Union and how they maintain compliance throughout the product's life cycle. Additionally, the new revision 4 of the clinical evaluation report guidance document (MEDDEV 2.7.1) severely restricts the use of substantial equivalence for new products, resulting in the need for formal clinical trial data for most new products. These changes will increase the cost for compliance and for product development, and they lengthen product introduction cycles. Failure to comply with these changes can have an adverse effect on our ability to release new products in a timely manner.

In order to maintain medical device sales in Canada, Iridex must obtain the ISO 13485:2016 certificate through the Medical Device Single Audit Program (MDSAP). This program allows a single audit of a medical device manufacturer's Quality Management Systems which satisfies the requirements of multiple regulatory jurisdictions. Specifically, MDSAP is a way that medical device manufacturers can be audited once for compliance with the standard and regulatory requirements of up to five different medical device markets: Australia, Brazil, Canada, Japan and the United States. The MDSAP audit program is voluntary in all countries except Canada. Iridex must pass comprehensive Stage I and Stage II audits and receive the ISO certificate by December 31, 2019 in order to continue to distribute product in Canada after that date.

Changes in existing requirements or adoption of new requirements or policies by the FDA or other foreign and domestic regulatory authorities could adversely affect our ability to comply with regulatory requirements. Failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition and results of operations. We may be required to incur significant costs to comply with laws and regulations in the future. These laws or regulations may have a material adverse effect upon our business, financial condition or results of operations.

Reimbursement

The cost of a significant portion of medical care in the United States is funded by government programs, health maintenance organizations and private insurance plans. Our ophthalmology products are typically purchased by doctors, clinics, hospitals and other users, which bill various third-party payers, such as government programs and private insurance plans, for the health care services provided to their patients. Government imposed limits on reimbursement of hospitals and other health care providers have significantly affected the spending budgets of doctors, clinics and hospitals to acquire new equipment, including our products. Under certain government insurance programs, a health care provider is reimbursed for a fixed sum for services rendered in treating a patient, regardless of the actual charge for such treatment. The Center for Medicare and Medicaid Services reimburses hospitals on a prospectively-determined fixed amount basis for the costs associated with an in-patient hospitalization based on the patient's discharge diagnosis, regardless of the actual costs incurred by the hospital or physician in furnishing the care and regardless of the specific devices used in that procedure.

Private third-party reimbursement plans are also developing increasingly sophisticated methods of controlling health-care costs by imposing limitations on reimbursable procedures and the exploration of more cost-effective methods of delivering health care. In general, these government and private measures have caused health care providers, including our customers, to be more selective in the purchase of medical products. In addition, changes in government regulation or in private third-party payers' policies may limit or eliminate reimbursement for procedures employing our products, which could have a material adverse effect on our business, results of operations and financial condition.

Doctors, clinics, hospitals and other users of our products may not obtain adequate reimbursement for use of our products from third-party payers. While we believe that the laser procedures using our products have generally been reimbursed, payers may deny coverage and reimbursement for our products if they determine that the device was not reasonable and necessary for the purpose used, was investigational or was not cost-effective.

Backlog and Seasonality

We generally do not maintain a material level of backlog. As a result, we do not believe that our backlog at any particular time is indicative of future sales levels. Our quarterly results have been, and are expected to continue to be, affected by seasonal factors. For example, our European sales during the third quarter are generally lower due to many businesses being closed for the summer vacation season.

Employees

As of December 29, 2018, we had a total of 114 full-time equivalent employees engaged in our ongoing operations, including 48 in operations (including manufacturing, quality, logistics and service), 40 in sales and marketing which does not include 4 consultants and one independent sales representative, 11 in R&D and 15 in finance and administration. We also employ, from time to time, a number of temporary and part-time employees as well as consultants on a contract basis. As of December 29, 2018, we had 38 such persons serving in such roles. Our future success will depend in part on our ability to attract, train, retain and motivate highly qualified employees, who are in great demand. We may not be successful in attracting and retaining such personnel. Our employees are not represented by a collective bargaining organization, and we have never experienced a work stoppage or strike. We consider our employee relations to be good.

Available Information

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to reports pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available, free of charge, through the U.S. Securities and Exchange Commission's ("SEC") website at www.sec.gov. These periodic reports and amendments are also available, free of charge, on our website at www.IRIDEX.com, as soon as reasonably practicable after such reports are electronically filed with the SEC.

Investors and others should note that we announce material financial information to our investors using SEC filings, press releases, our investor relations website, public conference calls and webcasts. We use these channels as well as social media to communicate with investors, customers and the public about our company, our products and other issues. It is possible that the information we post on social media channels could be deemed to be material information. We encourage investors, our customers, and others interested in IRIDEX to review the information we post on our Facebook page (www.facebook.com/IRIDEX) and Twitter feed (https://twitter.com/IRIDEX). Any information on, or that can be accessed through, our website and social media channels is not part of this report.

Item 1A. Risk Factors

Factors That May Affect Future Results

In addition to the other information contained in this Annual Report Form 10-K, we have identified the following risks and uncertainties that may have a material adverse effect on our business, common stock price, financial condition or results of operations. You should carefully consider the risks described below before making an investment decision.

Risks Relating to our Business

We face quality control and other production issues that could materially and adversely impact our sales and financial results and the acceptance of our products.

The manufacture of our infrared and visible laser consoles and related delivery devices is a highly complex and precise process. We may experience manufacturing difficulties, quality control issues or assembly constraints.

If our sales increase substantially, we may need to increase our production capacity and may not be able to do so in a timely, effective or cost-efficient manner. We may not be able to manufacture sufficient quantities of our products, which may require that we qualify other manufacturers for our products. Furthermore, we may experience delays, disruptions, capacity constraints or quality control problems in our manufacturing operations.

In the past several years, we have experienced supply chain, production and training issues as we have expanded our product lines and sales volumes, and may experience similar issues in the future as we continue to grow our business. These issues have caused, and may in the future cause, us to reduce or delay the shipment of our products and incur costs to service or replace products already shipped to customers. We have also incurred, and may in the future incur, additional costs to rectify or prevent similar issues in the future. Our efforts to address these supply chain, production and training issues may not be successful, and if we are unable to address these issues in a timely and cost-effective manner, product shipments to our customers could be delayed, our sales levels may suffer and manufacturing and operational costs may increase, any of which would negatively impact our business, results of operations and financial condition.

Some of our laser systems are complex in design and may contain defects that are not detected until deployed by our customers, which could increase our costs and reduce our revenues.

Laser systems are inherently complex in design and require regular maintenance. The manufacture of our lasers, laser products and systems involves a highly complex and precise process. As a result of the technical complexity of our products, changes in our or our suppliers' manufacturing processes or the inadvertent use of defective materials by us or our suppliers could result in a material adverse effect on our ability to achieve acceptable manufacturing yields and product reliability. To the extent that we do not achieve such yields or product reliability, our business, operating results, financial condition and customer relationships would be adversely affected. We provide warranties on certain of our product sales, and allowances for estimated warranty costs are recorded during the period of sale. The determination of such allowances requires us to make estimates of failure rates and expected costs to repair or replace the products under warranty. We currently establish warranty reserves based on historical warranty costs. If actual return rates and/or repair and replacement costs differ significantly from our estimates, adjustments to recognize additional cost of revenues may be required in future periods.

Our customers may discover defects in our products after the products have been fully deployed and operated under peak stress conditions. In addition, some of our products are combined with products from other vendors, which may contain defects. As a result, should problems occur, it may be difficult to identify the source of the problem. If we are unable to identify and fix defects or other problems, we could experience, among other things:

- loss of customers;
- increased costs of product returns and warranty expenses;
- damage to our brand reputation;
- failure to attract new customers or achieve market acceptance;
- diversion of development and engineering resources; and
- legal actions by our customers.

The occurrence of any one or more of the foregoing factors could seriously harm our business, financial condition and results of operations.

We rely on our direct and independent sales forces and network of international distributors to sell our products and any failure to maintain our sales force and distributor relationships could harm our business.

Our ability to sell our products and generate revenues depends upon our direct and independent sales forces within the United States, direct sales force in Germany and relationships with independent international distributors. Currently our direct and independent sales forces within the United States consist of approximately 20 employees and one independent representative, respectively and our direct sales force in Germany consists of 3 employees. Our international independent distributors are managed by a team of 6 people. We generally grant our distributors exclusive territories for the sale of our products in specified countries. The amount and timing of resources dedicated by our distributors to the sales of our products is not within our control. Our international sales are largely dependent on the efforts of these third parties. If any distributor breaches the terms of its distribution agreement with us or fails to generate sales of our products, we may be forced to replace the distributor and our ability to sell our products into that exclusive sales territory would be adversely affected.

We do not have any long-term employment contracts with the members of our direct sales force. We may be unable to replace our direct sales force personnel with individuals of equivalent technical expertise and qualifications, which may harm our revenues and our ability to maintain market share. Similarly, our independent and distributor agreements are generally terminable at will by either party and independents and distributors may terminate their relationships with us, which would affect our sales and results of operations. As we establish our direct sales capabilities in Germany, we may be unable to recruit and retain qualified personnel in this region. Any loss of the members of our existing direct or indirect sales organizations, or any failure to execute on our plans to further develop our sales function, could have an adverse impact on our business, results of operations and financial condition.

Growth in our sales and marketing organization may create operational challenges without immediately offsetting benefits.

We have increased and continue to increase our internal sales and marketing functions. This growth may place a significant strain on our management, operating and financial systems and our sales, marketing, training and administrative resources. As a result of our growth, our operating costs may escalate even faster than planned, and some of our internal systems may need to be enhanced or replaced. For example, if we are unable to provide adequate training for our expanding sales force, our ability to fully utilize new sales and marketing resources may be adversely impacted, we could suffer reputational harm and our ability to maintain our installed base of customers may be negatively impacted. If we cannot effectively manage our expanding operations and our costs, we may not be able to grow effectively or we may grow at a slower pace, and our business could be adversely affected.

It can take six months or longer before our internal sales representatives are fully trained and productive in selling our solution to prospective clients. This ramp period presents a number of operational challenges as the cost of recruiting, hiring and carrying new sales representatives cannot be offset by the revenue such new sales representatives produce until after they complete their ramp periods. If we cannot reliably develop our sales representatives to a productive level, or if we lose productive representatives in whom we have heavily invested, our future growth rates and revenue will suffer.

We depend on international sales for a significant portion of our operating results.

We derive, and expect to continue to derive, a large portion of our revenues from international sales. For the fiscal year ended December 29, 2018, our international sales were $20.5 million, or 48.1% of total revenues. We anticipate that international sales will continue to account for a significant portion of our revenues in the foreseeable future. All of our international revenues and costs for the year ended December 29, 2018 have been denominated in U.S. dollars except for a sale transacted through our German subsidiary. As a result, an increase in the value of the U.S. dollar relative to foreign currencies makes our U.S. dollar-denominated products more expensive and thus less competitive in foreign markets and may negatively affect our reported revenue in any particular reporting period. Our international

operations and sales are subject to a number of risks and potential costs, including:

- fluctuations in foreign currency exchange rates;
- product and production issues;
- performance of our international channel of distributors;
- longer accounts receivable collection periods;
- impact of recessions in global economies and availability of credit;
- political and economic instability;
- trade sanctions and embargoes;

- impact of international conflicts, terrorist and military activity, civil unrest;
- foreign certification requirements, including continued ability to use the “CE” mark in Europe, and other local regulatory requirements;
- differing local product preferences and product requirements;
- cultural differences;
    - changes in foreign medical reimbursement and coverage policies and programs;
- reduced or limited protections of intellectual property rights in jurisdictions outside the United States;
- potentially adverse tax consequences;
- protectionist, adverse and changing foreign governmental laws and regulations;
- greater risk of our employees failing to comply with both U.S. and foreign laws, including anti-trust regulations, the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act of 2010 and any trade regulations designed to ensure fair trade practices; and
- compliance costs and risks of non-compliance with multiple regulatory regimes governing the production, marketing, sale and use of our products.

Any one or more of these factors stated above could have a material adverse effect on our business, financial condition or results of operations.

As we expand our existing international operations, we may encounter new risks in addition to the above factors. For example, as we focus on building our international sales and distribution networks in new geographic regions, we must continue to develop relationships with qualified local distributors and trading companies. If we are not successful in developing these relationships, we may not be able to grow sales in these geographic regions. These or other similar risks could adversely affect our revenues, profitability and the price of our common stock.

If we fail to develop and successfully introduce new products and applications or fail to improve our existing products, our business prospects and operating results may suffer.

Our ability to generate incremental revenue growth will depend, in part, on the successful outcome of research and development activities, which may include clinical trials that lead to the development of new products and new applications using our products. Our research and development process is expensive, prolonged, and entails considerable uncertainty. Due to the complexities and uncertainties associated with ophthalmic research and development, products we are currently developing may not complete the development process or obtain the regulatory approvals required to market such products successfully.

Successful commercialization of new products and new applications will require that we effectively transfer production processes from research and development to manufacturing and effectively coordinate with our suppliers. In addition, we must successfully sell and achieve market acceptance of new products and applications and enhanced versions of existing products. The extent of, and rate at which, market acceptance and penetration are achieved by future products is a function of many variables, which include, among other things, price, safety, efficacy, reliability, marketing and sales efforts, the development of new applications for these products, the availability of third-party reimbursement of procedures using our new products, the existence of competing products and general economic conditions affecting purchasing patterns.

Our ability to market and sell new products is subject to government regulation, including approval or clearance by the FDA and foreign government agencies. Any failure in our ability to successfully develop and introduce new products or enhanced versions of existing products and achieve market acceptance of new products and new applications could have a material adverse effect on our operating results and would cause our net revenues to decline.

We are exposed to risks associated with worldwide economic slowdowns and related uncertainties.

We are subject to macro-economic fluctuations in the U.S. and worldwide economy. Concerns about consumer and investor confidence, volatile corporate profits and reduced capital spending, international conflicts, terrorist and military activity, civil unrest and pandemic illness could reduce customer orders or cause customer order cancellations. In addition, political and social turmoil related to international conflicts and terrorist acts may put further pressure on economic conditions in the United States and abroad.

Weak economic conditions and declines in consumer spending and consumption may harm our operating results. Purchases of our products are often discretionary. During uncertain economic times, customers or potential customers may delay, reduce or forego their purchases of our products and services, which may impact our business in a number of ways, including lower prices for our products and services and reducing or delaying sales. There could be a number of follow-on effects from economic uncertainty on our business, including insolvency of key suppliers resulting in product delays, delays in customer payments of outstanding accounts receivable and/or customer insolvencies, counterparty failures negatively impacting our operations, and increasing expense or inability to obtain future financing.

If economic uncertainty persisted, or if the economy entered a prolonged period of decelerating growth, our results of operations may be harmed.

Our operating results may fluctuate from quarter to quarter and year to year.

Our sales and operating results may vary significantly from quarter to quarter and from year to year in the future. Our operating results are affected by a number of factors, many of which are beyond our control. Factors contributing to these fluctuations include the following:

- changes in the prices at which we can sell our products, including the impact of changes in exchange rates;
- general economic uncertainties and political concerns;
- introduction of new products, product enhancements and new applications by our competitors, including new drugs, entry of new competitors into our markets, pricing pressures and other competitive factors;
- any delays or reductions in product shipments, or product recalls, resulting from manufacturing, distribution or other operational issues;
- the timing of the introduction and market acceptance of new products, product enhancements and new applications;
- changes in demand for our existing line of ophthalmology products;
- the cost and availability of components and subassemblies, including the willingness and ability of our sole or limited source suppliers to timely deliver components at the times and prices that we have planned;
- our ability to maintain sales volumes at a level sufficient to cover fixed manufacturing and operating costs;
- fluctuations in our product mix within ophthalmology products and foreign and domestic sales;
- the effect of regulatory approvals and changes in domestic and foreign regulatory requirements;
- our long and highly variable sales cycle;
- changes in customers' or potential customers' budgets as a result of, among other things, reimbursement policies of government programs and private insurers for treatments that use our products;
- variances in shipment volumes as a result of product, supply chain and training issues; and
- increased product innovation costs.

In addition to these factors, our quarterly results have been, and are expected to continue to be, affected by seasonal factors. For example, our European sales during the third quarter are generally lower due to many businesses being closed for the summer vacation season.

Our expense levels are based, in part, on expected future sales. If sales levels in a particular quarter do not meet expectations, we may be unable to adjust operating expenses quickly enough to compensate for the shortfall of sales, and our results of operations may be adversely affected. In addition, we have historically made a significant portion of each quarter's product shipments near the end of the quarter. If that pattern continues, any delays in shipment of products could have a material adverse effect on results of operations for such quarters. Due to these and other factors, we believe that quarter to quarter and year to year comparisons of our past operating results may not be meaningful. You should not rely on our results for any quarter or year as an indication of our future performance. Our operating results in future quarters and years may be below expectations, which would likely cause the price of our common stock to fall.

We rely on continued market acceptance of our existing products and any decline in sales of our existing products would adversely affect our business and results of operations.

We currently market visible and infrared medical laser systems and delivery devices to the ophthalmology market. We believe that continued and increased sales, if any, of these medical laser systems is dependent upon a number of factors including the following:

- acceptance of product performance, features, ease of use, scalability and durability, including with respect to our MicroPulse laser photocoagulation systems;
- recommendations and opinions by ophthalmologists, other clinicians, and their associated opinion leaders;
- marketing and clinical study outcomes;
- price of our products and prices of competing products and technologies, particularly in light of the current macro-economic environment where healthcare systems and healthcare operators are becoming increasingly price sensitive;
- availability of competing products, technologies and alternative treatments; and
- level of reimbursement for treatments administered with our products.

In addition, we derive a meaningful portion of our sales in the form of recurring revenues from selling consumable instrumentation, including our MP3 and EndoProbe devices. Our ability to increase recurring revenues from the sale of consumable products will depend primarily upon the features of our current products and product innovation, the quality of, ease of use and prices of our products, including the relationship to prices of competing products. The level of our service revenues will depend on the quality of service we provide and the responsiveness and the willingness of our customers to request our services rather than purchase competing products or services. Any significant decline in market acceptance of our products or our revenues derived from the sales of laser consoles, delivery devices, consumables or services may have a material adverse effect on our business, results of operations and financial condition.

We face strong competition in our markets and expect the level of competition to grow in the foreseeable future.

Competition in the market for laser systems and delivery devices used for ophthalmic treatment procedures is intense and is expected to increase. This market is also characterized by technological innovation and change. We compete by providing features and services that are valued by our customers such as: enhanced product performance and clinical outcomes, ease of use, durability, versatility, customer training services and rapid repair of equipment.

Our principal ophthalmic laser competitors are Alcon Inc. (Novartis AG), Bausch and Lomb (Valeant), Carl Zeiss Meditec AG, Ellex Medical Lasers, Ltd., Lumenis Ltd., Nidek Co. Ltd., Quantel Medical SA, and Topcon Corporation. We also compete with alternative glaucoma surgical device companies such as Alcon, Allergan, Glaukos, New World Medical and Ivantis. Pharmaceuticals represent alternative treatments to our laser procedures. Some of our principal pharmaceutical competitors are Alcon, Allergan, OSI Pharmaceuticals (Astellas), Pfizer, Regeneron, Roche (Genentech) and Valeant Pharmaceuticals. Some of our competitors have substantially greater financial, engineering, product development, manufacturing, marketing and technical resources than we do. Some companies also have greater name recognition than us and long-standing customer relationships. In addition, other medical device companies, academic and research institutions, or others, may develop new technologies or therapies, including medical devices, surgical procedures or pharmacological treatments and obtain regulatory approval for products utilizing such techniques that are more effective in treating the conditions targeted by us, or are less expensive than our current or future products. Our technologies and products could be rendered obsolete by such developments. Any such developments could have a material adverse effect on our business, financial condition and results of operations.

Our operating results may be adversely affected by uncertainty regarding healthcare reform measures and changes in third-party coverage and reimbursement policies.

Our products are typically purchased by doctors, clinics, hospitals and other users, which bill various third-party payers, such as governmental programs and private insurance plans, for the health care services provided to their patients. Changes in government legislation or regulation or in private third-party payers' policies toward reimbursement for procedures employing our products may prohibit adequate reimbursement. There have been a number of legislative and regulatory proposals to change the healthcare system, reduce the costs of healthcare and change medical reimbursement policies. Doctors, clinics, hospitals and other users of our products may decline to purchase our products to the extent there is uncertainty regarding reimbursement of medical procedures using our products and any healthcare reform measures. Further proposed legislation, regulation and policy changes affecting third-party reimbursement are likely. Among other things, Congress has in the past proposed changes to and the repeal of the Patient Protection and Affordable Care Act and the Health

Care and Education Reconciliation Act of 2010, collectively, the "Affordable Care Act", and the current U.S. presidential administration has announced certain policy changes that could impact the availability of benefits under the Affordable Care Act. At this time, it remains unclear whether there will be any changes made to or any repeal of the Affordable Care Act, with respect to certain of its provisions or in its entirety or related administrative policies. Various healthcare reform proposals have also emerged at the state level.

We are unable to predict what legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future at the state or federal level, or what effect such legislation or regulation may have on us. Furthermore, existing legislation and regulation related to the health care industry and third-party coverage reimbursement, including the Affordable Care Act, has been subject to judicial challenge, and may be subject to similar challenges from time to time in the future. Denial of coverage and reimbursement of our products, or the revocation or changes to coverage and reimbursement policies, could have a material adverse effect on our business, results of operations and financial condition.

Third-party payers are increasingly scrutinizing and continue to challenge the coverage of new products and the level of reimbursement for covered products. Doctors, clinics, hospitals and other users of our products may not obtain adequate reimbursement for use of our products from third-party payers. While we believe that the laser procedures using our products have generally been reimbursed, payers may deny coverage and reimbursement for our products if they determine that the device was not reasonable and necessary for the purpose used, was investigational or was not cost-effective.

If we fail to comply with healthcare laws, we could face substantial penalties and financial exposure, and our business, operations and financial condition could be adversely affected.

While we do not bill directly to Medicare, Medicaid or other third-party payors, because payment is in many cases available for our products from such payors, many healthcare laws place limitations and requirements on the manner in which we conduct our business (including our sales and promotional activities and interactions with healthcare professionals and facilities) and could result in liability and exposure for us. The laws that may affect our ability to operate include (i) the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as Medicare or Medicaid, (ii) federal false claims laws which prohibit, 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, and which may apply to entities like us if we provide coding and billing advice to customers, or under theories of "implied certification" where the government and qui tam relators may allege that device companies are liable where a product that was paid for by the government in whole or in part was promoted "off-label," lacked necessary clearance or approval, or failed to comply with good manufacturing practices or other laws; (iii) transparency laws and related reporting and disclosures requirements such as the federal Sunshine Act, now known as Open Payments; and/or (iv) state law equivalents of each of the above federal laws, including, without limitation anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, many of which differ from their federal counterparts in significant ways, thus complicating compliance efforts.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, exclusion from participation in government healthcare programs, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that their provisions are open to a variety of evolving interpretations and enforcement discretion. Open Payments, commonly known as the Sunshine Act, is a relatively new law, and compliance with this law has presented a number of challenges to companies such as ours, in terms of interpretation of the law and its implementation. Under the Sunshine

Act, Centers for Medicare & Medicaid Services (“CMS”) has the potential to impose penalties of up to $1.15 million per year for violations, depending on the circumstances, although enforcement has been negligible to date. Payments reported under the Sunshine Act also have the potential to draw scrutiny on payments to and relationships with physicians, which may have implications under the Anti-Kickback Statute and other healthcare laws. The risk that we are our being found in violation of these laws may be increased by the fact that we do not have a formal healthcare compliance program in place. Further, while safe harbors may in some instances be available and utilized by companies to reduce risks associated with the Anti-Kickback Statute and certain other healthcare laws, we have not necessarily utilized such safe harbors nor fully followed all elements required to claim the benefit of such safe harbors in all possible instances. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business.

We depend on collaborative relationships to develop, introduce and market new products, product enhancements and new applications.

We depend on both clinical and commercial collaborative relationships. We have entered into collaborative relationships with academic medical centers and physicians in connection with the research and innovation and clinical testing of our products. Commercially, we currently have a distribution and licensing agreement with Alcon for our GreenTip SoftTip Cannula. Sales of and royalties from the GreenTip SoftTip Cannula are dependent upon the sales performance of Alcon, which depends on their efforts and is beyond our control. The failure to obtain any additional future clinical or commercial collaborations and the resulting failure or success of such collaboration relationships could have a material adverse effect on our ability to introduce new products or applications and therefore could have a material adverse effect on our business, results of operations and financial condition.

If we cannot increase our sales volumes, reduce our costs or introduce higher margin products to offset potential reductions in the average unit price of our products, our operating results may suffer.

The average unit price of our products may decrease in the future in response to changes in product mix, competitive pricing pressures, new product introductions by our competitors or other factors. If we are unable to offset the anticipated decrease in our average selling prices by increasing our sales volumes or through new product introductions, our net revenues will decline. In addition, to maintain our gross margins we must continue to reduce the manufacturing cost of our products. If we cannot maintain our gross margins our business could be seriously harmed, particularly if the average selling price of our products decreases significantly without a corresponding increase in sales.

Our promotional practices are subject to extensive government scrutiny. We may be subject to governmental, regulatory and other legal proceedings relative to advertising, promotion, and marketing that could have a significant negative effect on our business.

We are subject to governmental oversight and associated civil and criminal enforcement relating to drug and medical device advertising, promotion, and marketing, and such enforcement is evolving and intensifying. In the United States, we are subject to potential enforcement from the FDA, the U.S. Federal Trade Commission, the Department of Justice, the CMS, other divisions of the Department of Health and Human Services and state and local governments. Other parties, including private plaintiffs, also are commonly bringing suit against pharmaceutical and medical device companies, alleging off-label marketing and other violations. We may be subject to liability based on the actions of individual employees and contractors carrying out activities on our behalf, including sales representatives who may interact with healthcare professionals.

If we fail to manage growth effectively, our business could be disrupted which could harm our operating results.

We have experienced and may in the future experience growth in our business, both organically and through the acquisition of businesses and products. We have made and expect to continue to make significant investments to enable our future growth through, among other things, new product innovation and clinical trials for new applications and products. We must also be prepared to expand our work force and to train, motivate and manage additional employees as the need for additional personnel arises. Our personnel, systems, procedures and controls may not be adequate to support our future operations. Any failure to effectively manage future growth could have a material adverse effect on our business, results of operations and financial condition.

We rely on patents and proprietary rights to protect our intellectual property and business.

Our success and ability to compete is dependent, in part, upon our proprietary information. We rely on a combination of patents, trade secrets, copyright and trademark laws, nondisclosure and other contractual agreements and technical measures to protect our intellectual property rights. We file patent applications to protect technology, inventions and

improvements that are significant to the development of our business. Our patent portfolio includes 20 active United States patents and 13 active foreign patents on the technologies related to our products and processes. In addition, we have 8 patent applications pending in the United States and 12 foreign patent applications pending. Our patent applications may not be approved. Any patents granted now or in the future may offer only limited protection against potential infringement and development by our competitors of competing products. Moreover, our competitors, many of which have substantial resources and have made substantial investments in competing technologies, may seek to apply for and obtain patents that will prevent, limit or interfere with our ability to make, use or sell our products either in the United States or in international markets. Patents have a limited lifetime and once a patent expires competition may increase.

In addition to patents, we rely on trade secrets and proprietary know-how which we seek to protect, in part, through proprietary information agreements with employees, consultants and other parties. Our proprietary information agreements with our employees and consultants contain industry standard provisions requiring such individuals to assign to us, without additional consideration, any inventions conceived or reduced to practice by them while employed or retained by us, subject to customary exceptions. Proprietary information agreements with employees, consultants and others may be breached, and we may not have adequate remedies for any breach. Also, our trade secrets may become known to or independently developed by competitors.

The laser and medical device industry is characterized by frequent litigation regarding patent and other intellectual property rights. Companies in the medical device industry have employed intellectual property litigation to gain a competitive advantage.

Numerous patents are held by others, including academic institutions and our competitors. Patent applications filed in the United States generally will be published eighteen months after the filing date. However, since patent applications continue to be maintained in secrecy for at least some period of time, both within the United States and internationally, we cannot provide assurance that our technology does not infringe any patents or patent applications held by third parties. We have, from time to time, been notified of, or have otherwise been made aware of, claims that we may be infringing upon patents or other proprietary intellectual property owned by others. If it appears necessary or desirable, we may seek licenses under such patents or proprietary intellectual property. Although patent holders commonly offer such licenses, licenses under such patents or intellectual property may not be offered or the terms of any offered licenses may not be reasonable.

Any claims, with or without merit, and regardless of whether we are successful on the merits, would be time-consuming, result in costly litigation and diversion of technical and management personnel, cause shipment delays or require us to develop non-infringing technology or to enter into royalty or licensing agreements. An adverse determination in a judicial or administrative proceeding and failure to obtain necessary licenses or develop alternate technologies could prevent us from manufacturing and selling our products, which would have a material adverse effect on our business, results of operations and financial condition.

If we lose key personnel or fail to integrate replacement personnel successfully, our ability to manage our business could be impaired.

Our future success depends upon the continued service of our key management, technical, sales, and other critical personnel. Our officers and other key personnel are employees-at-will, and we cannot provide assurance that we will be able to retain them. Key personnel have left our company in the past, and there likely will be additional departures of key personnel from time to time in the future. The loss of any key employee could result in significant disruptions to our operations, including adversely affecting the timeliness of product releases, the successful implementation and completion of company initiatives, and the results of our operations. Competition for these individuals is intense, and we may not be able to attract, assimilate or retain highly qualified personnel. Competition for qualified personnel in our industry and the San Francisco Bay Area, as well as other geographic markets in which we recruit, is intense and characterized by increasing salaries, which may increase our operating expenses or hinder our ability to recruit qualified candidates. In addition, the integration of replacement personnel could be time consuming, may cause additional disruptions to our operations, and may be unsuccessful.

Our ability to raise capital in the future may be limited, and future sales and issuances of securities could negatively affect our stock price and dilute the ownership interest of our existing investors.

Our business and operations may consume resources faster than we anticipate. We may need in the future to raise additional funds through future equity or debt financings to meet our operational needs and capital requirements for product development, clinical trials and commercialization and may subsequently require additional fundraising. Additional financing may not be available on favorable terms, if at all. If adequate funds are not available on acceptable terms, we may be unable to invest in future growth opportunities, which could seriously harm our business and operating results. Future sales or issuances of securities by us could decrease the value of our common stock, dilute stockholders' voting power and reduce future potential earnings per share.

To raise capital, we may sell common stock, convertible securities or other equity-linked securities in one or more transactions at prices and in a manner we determine from time to time. If we sell additional equity securities, our existing stockholders may be materially diluted. Additionally, new investors could gain rights, preferences and privileges senior to those of existing holders of our common stock. We may also issue debt securities, which may

impose restrictive covenants on our operations or otherwise adversely affect the holdings or the rights of our stockholders.

Sales or issuances of a substantial amount of securities, or the perception that such sales could occur, may adversely affect prevailing market prices for our common stock. As of December 29, 2018, we had 13,602,052 shares of common stock outstanding, all of which shares were, and continue to be, eligible for sale in the public market, subject in some cases to compliance with the requirements of Rule 144, including the volume limitations and manner of sale requirements. Future resales of our common stock by our existing stockholders could cause the market price of our common stock to decline.

As of December 29, 2018, holders of an aggregate of 982,742 shares of our common stock have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or our other stockholders. In addition, the shares of common stock subject to outstanding options and Restricted Stock Units under our