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.

Table of Contents

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 2008 Equity Incentive Plan and the shares reserved for future issuance under the Incentive Plan may become eligible for sale in the public markets in the future, subject to certain legal and control limitations.

We may sell shares or other securities in any offering at a price per share that is less than the price per share paid by existing investors, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by existing investors.

If we fail to accurately forecast demand for our product and component requirements for the manufacture of our product, we could incur additional costs or experience manufacturing delays and may experience lost sales or significant inventory carrying costs.

We use quarterly and annual forecasts based primarily on our anticipated product orders to plan our manufacturing efforts and determine our requirements for components and materials. It is very important that we accurately predict both the demand for our product and the lead times required to obtain or manufacture the necessary components, materials, and fully assembled products. Lead times for components and fully assembled products vary significantly and depend on numerous factors, including the specific supplier, the size of the order, contract terms and current market demand for such products. If we overestimate the demand for our product, we may have excess inventory, which would increase our costs. If we underestimate demand for our product and consequently, our components, materials and fully assembled products requirements, we may have inadequate inventory, which could interrupt our manufacturing, delay delivery of our product to our customers and result in the loss of customer sales. Any of these occurrences would negatively impact our business and operating results.

We depend on sole source or limited source suppliers.

We rely on third parties to manufacture substantially all of the components used in our products, including optics, laser diodes and crystals. We have some long term or volume purchase agreements with our suppliers and currently purchase components and fully-assembled products on a purchase order basis. Some of our suppliers and manufacturers are sole or limited sources. In addition, some of these suppliers are relatively small private companies whose operations may be disrupted or discontinued at any time. There are risks associated with the use of independent manufacturers, including the following:

- unavailability of shortages or limitations on the ability to obtain supplies of components and products in the quantities that we require;
- delays in delivery or failure of suppliers to deliver critical components and products on the dates we require;
- failure of suppliers to manufacture and assemble components and products to our specifications, and potentially reduced quality; and
- inability to obtain components and products at acceptable prices.

Our business and operating results may suffer from the lack of alternative sources of supply for critical sole and limited source components and fully-assembled products. The process of qualifying suppliers is complex, requires extensive testing with our products, and may be lengthy, particularly as new products are introduced. New suppliers would have to be educated in our production processes. In addition, the use of alternate components may require design alterations to our products and additional product testing under FDA and relevant foreign regulatory agency guidelines, which may delay sales and increase product costs. Any failures by our vendors to adequately supply limited and sole source components or products may impair our ability to offer our existing products, delay the submission of new products for regulatory approval and market introduction, materially harm our business and financial condition and cause our stock price to decline. Establishing our own capabilities to manufacture these components or products would be expensive and could significantly decrease our profit margins. Our business, results of operations and financial condition would be adversely affected if we are unable to continue to obtain components or fully-assembled products in the quantity and quality desired and at the prices we have budgeted.

If our facilities were to experience catastrophic loss, our operations would be seriously harmed.

Our facilities could be subject to catastrophic loss such as fire, flood or earthquake. All of our research and development activities, manufacturing, our corporate headquarters and other critical business operations are located near major earthquake faults in Mountain View, California. Any such loss at any of our facilities could disrupt our operations, delay production, shipments and revenue and result in large expense to repair and replace our facilities.

If we experience a significant disruption in our information technology systems or breaches of data security, our business could be adversely affected.

We rely on information technology systems to keep financial records and corporate records, communicate with staff and external parties and operate other critical functions, including sales and manufacturing processes. Our information technology systems are potentially vulnerable to disruption due to breakdown or malicious intrusion and computer viruses. If we were to experience a prolonged system disruption in our information technology systems, it could negatively impact the coordination of our sales, planning and manufacturing activities, which could adversely affect our business. In addition, in order to maximize our information technology efficiency, we have physically consolidated our primary corporate data and computer operations. This concentration, however, exposes us to a greater risk of disruption to our internal information technology systems. Although we maintain offsite back-ups of our data, if operations at our facilities were disrupted, it may cause a material disruption in our business if we are not capable of restoring function on an acceptable time frame.

In addition, our information technology systems are potentially vulnerable to cyber-attacks or other data security breaches-whether by employees or others-which may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of sensitive and confidential information of our employees, customers, suppliers and others, any of which could have a material adverse effect on our business, financial condition and results of operations.

While we have implemented a number of protective measures, including firewalls, antivirus and malware detection tools, patches, log monitors, routine back-ups, system audits, routine password modifications and disaster recovery procedures, such measures may not be adequate or implemented properly to prevent or fully address the adverse effect of such events, and in some cases we may be unaware of an incident or its magnitude and effects. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above.

If we fail to maintain our relationships with health care providers, customers may not buy our products and our revenue and profitability may decline. At the same time, relationships with these individuals and entities are the subject of heightened scrutiny and may present the potential for healthcare compliance risks.

We market our products to numerous health care providers, including physicians, hospitals, ASCs, government affiliated groups and group purchasing organizations. We have developed and strive to maintain close relationships with members of each of these groups who assist in product research and development and advise us on how to satisfy the full range of surgeon and patient needs. We rely on these groups to recommend our products to their patients and to other members of their organizations. The failure of our existing products and any new products we may introduce to retain the support of these various groups could have a material adverse effect on our business, financial condition and results of operations. In addition, our interactions, communications, and financial relationships with these individuals and entities present potential healthcare compliance risks.

We are subject to government regulations which may cause us to delay or withdraw the introduction of new products or new applications for our products.

The medical devices that we market and manufacture are subject to extensive regulation by the FDA and by foreign and state governments. Under the FD&C Act and the related regulations, the FDA regulates the design, development, clinical testing, manufacture, labeling, sale, distribution and promotion of medical devices. Before a new device can be introduced into the market, the product must be shown to meet regulatory requirements established by the FD&C Act and implemented by the FDA. Unless otherwise exempt, a device manufacturer must obtain marketing “clearance” through the 510(k) premarket notification process, or “approval” through the lengthier premarket approval application

("PMA") process. Not all devices are eligible for the 510(k) clearance process. Depending upon the type, complexity and novelty of the device and the nature of the disease or disorder to be treated, the FDA process can take several years, require extensive clinical testing and result in significant expenditures. Even if regulatory clearance or approval is obtained, later discovery of previously unknown safety issues may result in restrictions on the product, including withdrawal of the product from the market. Other countries also have extensive regulations regarding clinical trials and testing prior to new product introductions. Our failure to obtain government approvals or any delays in receipt of such approvals would have a material adverse effect on our business, results of operations and financial condition.

The FDA imposes a broad range of additional requirements on medical device companies. Our products must be produced in compliance with the Quality System Regulation ("QSR") and our manufacturing facilities are subject to establishment registration and device listing requirements from the FDA, and similar requirements from certain state authorities, and ongoing periodic inspections by the FDA, including unannounced inspections for compliance with applicable requirements. We are subject to monitoring, recordkeeping, and reporting obligations for medical device adverse events and malfunctions; notification of our products' defects or failure to comply with the FDA's laser regulations; and reporting of recalls, corrections, or removals of our products. The FDA also imposes requirements for the labeling of our products, and places limitations on claims we are permitted to make about our products in promotional labeling. The Federal Trade Commission has jurisdiction over the advertising of all of our products, which are non-restricted devices, and exercises oversight in coordination with the FDA.

Noncompliance with the applicable requirements can result in, among other things, regulatory citations (including "483 Observations") and Warning Letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, withdrawal of marketing approvals, and criminal prosecution. The FDA also has the authority to request repair, replacement or refund of the cost of any device we manufacture or distribute. Any of these actions by the FDA would materially and adversely affect our ability to continue operating our business and the results of our operations. Such enforcement action can also result in negative publicity.

In addition, we are also subject to 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 with the European Medical Device Directives and all applicable standards. While currently all of our released products are CE marked, continued certification is based on the successful review of our quality system by our European Registrar during their annual audit. Any loss of certification would have a material adverse effect on our business, results of operations and financial condition. There are a number of major regulatory changes occurring in the regulation of medical devices in the EU. 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 EU 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.

Further, in order to maintain medical device sales in Canada, we must obtain the ISO 13485:2016 certificate through the MDSAP. MDSAP allows a single audit of a medical device manufacturer's Quality Management Systems which satisfies the requirements of multiple regulatory jurisdictions - Australia, Brazil, Canada, Japan and the United States. The MDSAP audit program is voluntary in all countries except Canada. MDSAP may impose a higher compliance burden than the CE Mark through more rigorous audit requirements. If we do not comply with the new MDSAP standard, we will not be able to sell our products in Canada after December 31, 2019.

Any clinical trials necessary that we may undertake for regulatory approval or marketing reasons will be an expensive, lengthy, costly, and uncertain process, and could result in delays in new product introductions or even an inability to release a product.

We may be required to undertake clinical trials often required to obtain regulatory approvals or may choose to undertake such trials for marketing or other reasons. Clinical trials for products such as ours are complex and expensive and their outcomes are uncertain. Any clinical trials that we may undertake would require the investment of significant financial and administrative resources. Moreover, the results of clinical trials are uncertain, and inconclusive or negative results may not support, or may impair, the sale and adoption of our products. We may suffer

significant setbacks in clinical trials, even after earlier clinical trials showed promising results. Any of our products could produce undesirable side effects that could cause us or regulatory authorities to interrupt, delay or halt clinical trials of a product candidate. We, the FDA, or another regulatory authority could suspend or terminate clinical trials at any time if they or we believed the trial participants faced unacceptable health risks.

If we fail to comply with the FDA's quality system regulation and laser performance standards, our manufacturing operations could be halted, and our business would suffer.

We are currently required to demonstrate and maintain compliance with the FDA's QSR. The QSR is a complex regulatory scheme that covers the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping of our products. Because our products involve the use of lasers, our products also are covered by a performance standard for lasers set forth in FDA regulations. The laser performance standard imposes specific record-keeping, reporting, product testing and product labeling requirements. These requirements include affixing warning labels to laser products, as well as incorporating certain safety features in the design of laser products. The FDA enforces the QSR and laser performance standards through periodic unannounced inspections. We have been, and anticipate in the future being, subject to such inspections. Our failure to take satisfactory corrective action in response to an adverse

QSR inspection or our failure to comply with applicable laser performance standards could result in enforcement actions, including a public warning letter, a shutdown of our manufacturing operations, a recall of our products, civil or criminal penalties, or other sanctions, which would cause our sales and business to suffer.

If we modify one of our FDA cleared devices, we may need to submit a new 510(k), or potentially a PMA, and if clearance or approval is not obtained, it would prevent us from selling our modified products or cause us to redesign our products.

Any modifications to an FDA-cleared device that would significantly affect its safety or effectiveness or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a PMA. We may not be able to obtain additional 510(k) clearances or premarket approvals for new products or for modifications to, or additional indications for, our existing products in a timely fashion, or at all. Delays in obtaining future clearances would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenues and future profitability. We have made modifications to our devices in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees, and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing the modified devices, which could harm our operating results and require us to redesign our products.

Our products may be misused, which could harm our reputation and our business.

We market and sell our products for use by highly skilled physicians with specialized training and experience in the treatment of eye-related disorders. We, and our distributors, generally offer but do not require purchasers or operators of our products to attend training sessions, nor do we supervise the procedures performed with our products. The physicians who operate our products are responsible for their use and the treatment regime for each individual patient. In addition, non-physicians, particularly in countries outside of the United States, or poorly trained or inexperienced physicians, may make use of our products. Our efforts to market our MicroPulse systems as a Fovea-friendly alternative to traditional continuous wavelength systems or alternative treatment methods may result in users failing to implement adequate safety precautions and thereby increase the risks associated with the misuse of our product. The lack of training and the purchase and use of our products by non-physicians or poorly trained or inexperienced physicians may result in product misuse and adverse treatment outcomes, which could harm our reputation and expose us to costly product liability litigation, or otherwise cause our business to suffer.

Inability of customers to obtain credit or material increases in interest rates may harm our sales.

Some of our products are sold to health care providers in general practice. Many of these health care providers purchase our products with funds they secure through various financing arrangements with third-party financial institutions, including credit facilities and short-term loans. If availability of credit becomes more limited, or interest rates increase, these financing arrangements may be harder to obtain or become more expensive for our customers, which may decrease demand for our products. Any reduction in the sales of our products would cause our business to suffer.

Our products could be subject to recalls even after receiving FDA approval or clearance. A recall would harm our reputation and adversely affect our operating results.

The FDA and similar governmental authorities in other countries in which we market and sell our products have the authority to require the recall of our products in the event of material deficiencies or defects in the design or manufacture of our products, or in other cases we may determine that we will recall a product because we have determined that the product is violative, in order to avoid further enforcement action and protect the public health.

A government mandated recall, or a voluntary recall by us, could occur as a result of actual or potential component failures, adverse event reports, manufacturing errors or design defects, including defects in labeling. Furthermore, we may from time to time initiate a recall of a component or set of components comprising a portion of our laser systems, which could increase customer returns, warranty claims and associated reserve levels. A recall could divert management's attention, cause us to incur significant expenses, harm our reputation with customers and negatively affect our future sales and financial results.

For example, on February 23, 2018, we initiated a worldwide voluntary recall of a specific laser accessory called the TruFocus LIO Premiere™ ("LIO"). The LIO is a head-mounted indirect ophthalmoscope that connects to our laser console and is used to view and perform laser treatment on a patient's retina. This recall was prompted after we received reports of three adverse events from one physician in the U.S., resulting in focal cataracts and iris burns occurring during procedures in which the TruFocus LIO Premiere was used. We identified several potential root causes for the adverse events, including use error. The recall is still in progress and expected to be completed by end of first quarter of fiscal year 2019.

We recently obtained FDA clearance for an updated TruFocus LIO Premiere™ device. The updated device includes expanded user instructions and minor design changes. Use of the updated LIO may result in adverse events, including those observed with the prior LIO device. If physician use of our updated LIO results in serious adverse events, we may have to initiate another recall or utilize additional resources to further evaluate the design of the LIO device. Furthermore, in light of the recall, we cannot provide any assurance that the updated LIO, once launched, will achieve market acceptance. We will be

required to devote significant resources to launch and market the updated LIO and cannot provide any assurance that these activities will generate revenue as anticipated. If our revenue grows more slowly than we expect because of a delay in or a lack of market acceptance for our updated LIO, our business and financials will be adversely affected.

If product liability claims are successfully asserted against us, we may incur substantial liabilities that may adversely affect our business or results of operations.

We may be subject to product liability claims from time to time. Our products are highly complex and some are used to treat extremely delicate eye tissue. We believe we maintain adequate levels of product liability insurance. However, product liability insurance is expensive and we might not be able to obtain product liability insurance in the future on acceptable terms or in sufficient amounts to protect us, if at all. A successful claim brought against us in excess of our insurance coverage could have a material adverse effect on our business, results of operations and financial condition.

Significant developments resulting from recent and potential changes in United States trade policies could have a material adverse effect on us.

Certain of our materials may be subject to the effects of various trade agreements, treaties and tariffs. The current U.S. presidential administration has publicly stated its intention to renegotiate or withdraw from the North American Free Trade Agreement and has imposed tariffs on various goods from various countries, including China, Canada and the European Union (“EU”), and announced intentions to impose furthermore significant tariffs on certain United States imports. As a result, Canada, the EU, China and other countries have responded with retaliatory tariffs on certain United States exports. We cannot predict the effect these and potential additional tariffs will have on our business, including in the context of escalating trade tensions. Further tariffs, additional taxes, or trade barriers, both domestically and internationally, may affect our selling and/or manufacturing costs and margins, the competitiveness of our products, or our ability to sell products or purchase necessary equipment and supplies, and consequently affect our business, results of operations, or financial conditions. To the extent that trade tariffs and other restrictions imposed by the United States increase the price of, or limit the amount of, raw materials and finished goods imported into the United States, the costs of our raw materials may be adversely affected and the demand from our customers for products and services may be diminished, which could adversely affect our revenues and profitability.

In addition, these potential developments and any market perceptions concerning these and related issues and the attendant regulatory uncertainty regarding, for example, the posture of governments with respect to international trade, could have a material adverse effect on global trade and economic growth which, in turn can adversely affect our business. Furthermore, changes in United States trade policy have resulted and could result in additional reactions from United States trading partners and other countries, including adopting responsive trade policies that make it more difficult or costly for us to export our products to those countries. We sell a significant majority of our products into countries outside the United States and we purchase a significant portion of equipment and supplies from suppliers outside the United States. These measures could also result in increased costs for goods imported into the U.S. or may cause us to adjust our worldwide supply chain. Any of these effects could require us to increase prices to our customers which may reduce demand, or, if we are unable to increase prices, may result in lowering our margin on products sold.

We cannot predict future trade policy or the terms of any renegotiated trade agreements and their impacts on our business. The adoption and expansion of trade restrictions, the occurrence of a trade war, or other governmental action related to tariffs or trade agreements or policies has the potential to adversely impact demand for our products, our costs, our customers, our suppliers, and the United States economy, which in turn could adversely impact our business, financial condition and results of operations.

Changes in U.S. tax laws could have a material adverse effect on our business, cash flow, results of operations or financial conditions.

The comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "Tax Act") was enacted in the United States on December 22, 2017 and includes, among other items, a reduction in the federal corporate income tax rate from 35% to 21%, certain interest expense deduction limitations and changes in the timing of certain taxable income. We are required to recognize the effect of the tax law changes in the period of enactment, such as remeasuring our U.S. deferred tax assets and liabilities and reassessing the net realizability of our deferred tax assets and liabilities.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118 ("SAB 118") which provides guidance on accounting for the tax effects of the Tax Act. We have completed our analysis and accounting with respect the Tax Act, and identified no additional changes from amounts previously recorded. However, changes in law, interpretations, and facts may result in adjustments to these amounts. Based on the Company's net operating loss carryovers and valuation allowance, there is no impact to its consolidated financial statements as a result of the accounting for the tax effects of the Tax Act.

Subsequent legislations, guidance, regulations or audits that differ from our prior assumptions and interpretations, or other factors which were not anticipated at the time we estimated our tax provision could have a material adverse effect on our business, cash flow, results of operations or financial condition.

We are subject to federal, state and foreign laws governing our business practices which, if violated, could result in substantial penalties. Additionally, challenges to or investigation into our practices could cause adverse publicity and be costly to respond to and thus could harm our business.

The Dodd-Frank Wall Street Reform and Consumer Protection Act requires us to track and disclose the source of certain metals used in manufacturing which may stem from minerals (so called “conflict minerals”) which originate in the Democratic Republic of the Congo or adjoining regions. These metals include tantalum, tin, gold and tungsten. These metals are central to the technology industry and are present in some of our products as component parts. In most cases no acceptable alternative material exists which has the necessary properties. It is not possible to determine the source of the metals by analysis but instead a good faith description of the source of the intermediate components and raw materials must be obtained. The components which incorporate those metals may originate from many sources and we purchase fabricated products from manufacturers who may have a long and difficult-to-trace supply chain. As the spot price of these materials varies, producers of the metal intermediates can be expected to change the mix of sources used, and components and assemblies which we buy may have a mix of sources as their origin. We are required to carry out a diligent effort to determine and disclose the source of these materials. There can be no assurance we can obtain this information from intermediate producers not willing or not able to provide this information or further identify their sources of supply or to notify us if these sources change. These metals are subject to price fluctuations and shortages which can affect our ability to obtain the manufactured materials we rely on at favorable terms or from consistent sources. These changes could have an adverse impact on our ability to manufacture and market our devices and products.

Efforts to acquire additional companies or product lines may divert our managerial resources away from our business operations, and if we complete additional acquisitions, we may incur or assume additional liabilities or experience integration problems.

As part of our growth strategy, we seek to acquire businesses or product lines for various reasons, including adding new products, adding new customers, increasing penetration with existing customers, adding new manufacturing capabilities or expanding into new geographic markets. Our ability to successfully grow through acquisitions depends upon our ability to identify, negotiate, complete and integrate suitable acquisitions and to obtain any necessary financings. These efforts could divert the attention of our management and key personnel from our business operations. If we complete future acquisitions, we may also experience:

- difficulties integrating any acquired products into our existing business;
- difficulties in integrating an acquired company’s technologies, services, employees, customers, partners, business operations and administrative and software management systems with ours;
- delays in realizing the benefits of the acquired products;
- diversion of our management’s time and attention from other business concerns;
- adverse customer reaction to the product acquisition; and
- increases in expenses.

Moreover, we cannot assure you that the anticipated benefits of any acquisition or investment would be realized or that we would not be exposed to unknown liabilities. In connection with these types of transactions, we may issue additional equity securities that would dilute the ownership interest of existing investors or earnings per share, use cash that we may need in the future to operate our business, incur debt on terms unfavorable to us or that we are unable to repay, incur large charges or substantial liabilities, encounter difficulties integrating diverse business cultures and become subject to adverse tax consequences, substantial depreciation or deferred compensation charges. These challenges related to acquisitions or investments could adversely affect our business, operating results and financial condition.

Divestitures of some of our businesses or product lines may materially and adversely affect our financial condition, results of operations or cash flows and require us to raise additional capital to replace revenue from those business units or product lines.

We evaluate the performance and strategic fit of all of our businesses and may sell businesses or product lines. Divestitures involve risks, including difficulties in the separation of operations, services, products and personnel, the diversion of management's attention from other business concerns, the disruption of our business, the potential loss of key employees and the retention of uncertain environmental or other contingent liabilities related to the divested business. In addition, divestitures may result in significant asset impairment charges, including those related to goodwill and other intangible assets, and the loss of revenue which could have a material adverse effect on our financial condition and results of operations. In addition, we may need to raise additional capital to replace the revenue generated from the business or product line that is divested and we can provide no assurance that such capital will be available or available on terms that are acceptable to us. We cannot assure you that we will be successful in managing these or any other significant risks that we encounter in divesting a business or product line, and any divestiture we undertake could materially and adversely affect our

business, financial condition, results of operations and cash flows, and may also result in a diversion of management attention, operational difficulties and losses.

If we fail to comply with environmental requirements, our business, financial condition, operating results and reputation could be adversely affected.

Our products and operations are subject to various federal, state, local and foreign environmental laws and regulations, including those governing the use, storage, handling, exposure to, and disposal of hazardous materials and a large and growing body of international standards which govern the design, manufacture, materials content and sourcing, testing, certification, packaging, installation, use and disposal of our products. We must continually keep abreast of these standards and requirements and integrate compliance to these with the development and regulatory documentation for our products. Failure to meet these standards could limit the ability to market our products in those regions which require compliance with such standards or subject us to fines and penalties. Examples of such standards include laws governing the hazardous material content of our devices and products, such as the EU Directive 2011/65/EU relating to Restrictions on the Use of Certain Hazardous Substances “RoHS Directive, and the EU Directive 2012/19/EU on Waste Electrical and Electronic Equipment. Similar laws and regulations have been passed or are pending in several other jurisdictions and may be enacted in other regions, including in the United States, and we are, or may in the future be, subject to these laws and regulations.

Our failure to comply with past, present and future similar laws could result in reduced sales of our devices and products, inventory write-offs, reputational damage, penalties and other sanctions, any of which could harm our business and financial condition. We also expect that our devices and products will be affected by new environmental laws and regulations on an ongoing basis. New environmental laws and regulations will likely result in additional costs and may increase penalties associated with violations or require us to change the content of our devices and products or how they are manufactured, which could have a material adverse effect on our business, operating results and financial condition.

Risks Relating to Ownership of Our Common Stock

Our stock price has been and may continue to be volatile and an investment in our common stock could suffer a decline in value.

The trading price of our common stock has been subject to wide fluctuations in response to a variety of factors, some of which are beyond our control, including changes in foreign currency exchange rates, quarterly variations in our operating results, announcements by us or our competitors of new products or of significant clinical achievements, changes in market valuations of other similar companies in our industry and general market conditions. During the fiscal year ended December 29, 2018, the trading price of our common stock fluctuated from a low of $3.85 per share to a high of $9.15 per share. During the fourth fiscal quarter ended December 29, 2018, the trading price of our common stock fluctuated from $3.85 per share to a high of $6.30 per share. There can be no assurance that our common stock trading price will not suffer declines. Our common stock may experience an imbalance between supply and demand resulting from low trading volumes and therefore broad market fluctuations could have a significant impact on the market price of our common stock regardless of our performance.

Because we do not intend to pay dividends, stockholders will benefit from an investment in our common stock only if it appreciates in value.

We expect to retain any earnings for use to further develop our business, and do not expect to declare cash dividends on our common stock in the foreseeable future. The declaration and payment of any such dividends in the future depends upon our earnings, financial condition, capital needs and other factors deemed relevant by the board of directors, and may be restricted by future agreements with lenders. In addition, our loan facility with Silicon Valley Bank restricts us from paying any dividends or making any other distribution or payment on account of our common

stock. As a result, the success of an investment in our common stock will depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

If securities or industry analysts do not continue to publish research or publish incorrect or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us, our market and our competitors. If no or few securities or industry analysts cover our company, the trading price for our stock could be negatively impacted. If one or more of the analysts who covers us downgrades our stock or publishes incorrect or unfavorable research about our business, our stock price could decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price or trading volume to decline.

Ownership of our common stock is concentrated among a few investors, which may affect the ability of a third party to acquire control of us. Substantial sales by such investors could cause our stock price to decline.

Our directors, executive officers, current five percent or greater stockholders and affiliated entities together beneficially own a significant portion of our common stock outstanding as of December 29, 2018. Having such a concentration of ownership may have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from seeking to acquire, a majority of our outstanding common stock or control of our board of directors through a proxy solicitation.

As a public company, we are obligated to develop and maintain proper and effective internal control over financial reporting. We may not complete our analysis of our internal control over financial reporting in a timely manner, or these internal controls may not be determined to be effective, which may adversely affect investor confidence in our company and, as a result, the value of our common stock.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment must include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. We may experience difficulty in meeting these reporting requirements in a timely manner, particularly if material weaknesses or significant deficiencies were to persist. As of June 30, 2018, we became a “smaller reporting company” as defined in the Exchange Act, and effective with our Annual Report covering our fiscal year 2018, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. If we are unable to comply with the requirements of Section 404 in a timely manner, the market price of our stock could decline and we could be subject to sanctions or investigations by the Nasdaq Stock Market, the SEC or other regulatory authorities, which could require additional financial and management resources.

Any failure to develop or maintain effective controls, or any difficulties encountered in their implementation or improvement, could harm our operating results or cause us to fail to meet our reporting obligations. Any failure to implement and maintain effective internal controls also could adversely affect the results of periodic management evaluations regarding the effectiveness of our internal control over financial reporting. Ineffective disclosure controls and procedures or internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which could likely have a negative effect on the trading price of our common stock.

Implementing any appropriate changes to our internal controls may require specific compliance training of our directors, officers and employees, entail substantial costs in order to modify our existing accounting systems, and take a significant period of time to complete. Such changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and could materially impair our ability to operate our business. In the event that we are not able to demonstrate compliance with Section 404 of the Sarbanes-Oxley Act in a timely manner, that our internal controls are perceived as inadequate or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and our stock price could decline.

Our charter documents, anti-takeover provisions of Delaware law, and contractual provisions could delay or prevent an acquisition or sale of our company.

Our certificate of incorporation empowers the board of directors to establish and issue a class of preferred stock, and to determine the rights, preferences and privileges of the preferred stock. These provisions give the board of directors the ability to deter, discourage or make more difficult a change in control of our company, even if such a change in control could be deemed in the interest of our stockholders or if such a change in control would provide our stockholders with a substantial premium for their shares over the then-prevailing market price for the common stock.

Our certificate of incorporation and bylaws contain other provisions that could have an anti-takeover effect, including the following:

- the authorized number of directors may be changed only by resolution of our board of directors;
- only our board of directors is authorized to fill vacant directorships, including newly created seats;
- special meetings of our stockholders may be called only by our board of directors, the chairman of the board, chief executive officer or president, thus prohibiting a stockholder from calling a special meeting;
- stockholders must give advance notice to nominate directors or propose other business; and
- stockholders are not permitted to cumulate votes in the election of directors.

In addition, we are generally subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock or prevent changes in our management.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We lease a 37,166 square feet facility in Mountain View, California pursuant to a lease that is scheduled to expire in February 2022.

This facility is being substantially utilized for all of our manufacturing, research and development efforts and also serves as our corporate headquarters. Management believes that these facilities are adequate for our current needs and that suitable additional space or an alternative space would be available as needed in the future on commercially reasonable terms.

Item 3. Legal Proceedings

In January 2018, we filed a lawsuit against Quantel Medical, S.A., Quantel USA, Inc., and Quantel, S.A. (collectively, "Quantel") in the U.S. District Court for the Northern District of California. The lawsuit alleges that Quantel products infringe U.S. Patent No. 7,771,417, that Quantel breached an earlier agreement between Quantel and the Company, and that Quantel has infringed upon the Company's MicroPulse® trademark, Registration No. 4550188 on the principal register. Quantel previously had a limited license to the asserted Company patent and trademark. Our complaint filed in connection with this matter asserts that the license was terminated in early 2017 for material breach, but that Quantel continued to use our intellectual property without authorization.

In March 2017, OD-OS GmbH noticed an opposition to the Company's European Patent No. currently EP 1 856 774 at the European Patent Office ("EPO"). On June 8, 2018, Quantel intervened in the Opposition. Oral proceedings on the opposition took place on July 13, 2018. At the conclusion of those proceedings, the EPO's Opposition Division communicated that it would move to revoke the patent. The formal written decision from the Opposition Division was issued on October 1, 2018. The Company filed its notice of appeal on October 10, 2018.

In late May of 2018, Quantel applied to the Paris District Court in Paris, France for a ruling that its products do not infringe the French Part of Iridex's European Patent at issue in the opposition, EP 1 856 774.

On February 12, 2019, we announced the resolution of our dispute with Quantel and dismissed the lawsuit we filed against Quantel in the U.S. District Court for the Northern District of California. Quantel dismissed and ceased its participation in parallel proceedings against us in Europe.

In addition, from time to time, we may be involved in legal proceedings arising in the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, we currently believe that the final outcome of these ordinary course matters will not have a material adverse effect on our business, operating results, financial condition or cash flows. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. Mine Safety Disclosures

Not applicable.

30

PART II

Item 5. Market for Registrant's Common Equity and Related Stockholder Matters, and Issuer Purchases of Equity Securities

Market Information for Common Equity

Our common stock is currently quoted on the Nasdaq Global Market under the symbol "IRIX". The following table sets forth for the periods indicated the high and low sales prices for our common stock, as reported on the Nasdaq Global Market in fiscal years 2017 and 2018.

	High	Low
Fiscal 2018		
Fourth Quarter	$6.30	$3.85
Third Quarter	$9.15	$6.00
Second Quarter	$7.24	$5.33
First Quarter	$8.28	$5.72
Fiscal 2017		
Fourth Quarter	$9.94	$7.62
Third Quarter	$10.25	$8.19
Second Quarter	$11.52	$8.95
First Quarter	$15.99	$11.87

On March 14, 2019, the closing price for our common stock on the Nasdaq Global Market was $4.53 per share. As of March 14, 2019, there were approximately 35 holders of record (not in street name) of our common stock. Because many of our shares of common stock are held by brokers and other institutions on behalf of our stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Dividend Policy

We have never paid cash dividends on our common stock. We currently intend to retain any earnings for use in our business and do not anticipate paying cash dividends in the foreseeable future.

Sales of Unregistered Securities

None.

Use of Proceeds

On September 18, 2018, we sold 1,916,667 shares of the Company's common stock (including 250,000 shares of common stock from the exercise of the overallotment option of shares granted to the underwriters) at a price of $6.00 per share. The offer and sale of all of the shares in the public offering were registered under the Securities Act pursuant to a registration statement on Form S-3 (File No. 333- 213094). We entered into an underwriting agreement with underwriters for whom Stifel, Nicolaus & Company, Incorporated acted as representative. The net proceeds to the Company after deducting estimated underwriting discounts and commissions, fees and expenses of approximately $1.0 million were approximately $10.5 million. There has been no material change in the planned use of proceeds as

described in our final prospectus filed with the SEC on September 14, 2018 pursuant to Rule 424(b) of the Securities Act. We invested the funds received in registered money market funds.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Not applicable.

Item 6. Selected Financial Data

As a “smaller reporting company,” as defined in Rule 12b-2 of the Exchange Act, we are not required to provide the information called for by this Item.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

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:

- Glaucoma – Probes used in our glaucoma product line include our recently patented MicroPulse P3 ("MP3") probe, G-Probe and G-Probe Illuminate; 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 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, through independent distributors. 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.

Cost of revenues consists primarily of the cost of components and sub-systems, assembling, packaging, shipping and testing components at our facility, direct labor and associated overhead, warranty, royalty and amortization of intangible assets and depot service costs.

Research and development expenses consist primarily of personnel costs, materials to support new product development and research support provided to clinicians at medical institutions developing new applications which utilize our products and regulatory expenses. Research and development costs have been expensed as incurred.

Sales and marketing expenses consist primarily of costs of personnel, sales commissions, travel expenses, advertising and promotional expenses.

General and administrative expenses consist primarily of costs of personnel, legal, accounting and other public company costs, insurance and other expenses not allocated to other departments.

Results of Operations - 2018 and 2017

Our fiscal year ends on the Saturday closest to December 31. Fiscal 2018 ended on December 29, 2018 and fiscal 2017 ended on December 30, 2017. Fiscal years 2018 and 2017 each included 52 weeks of operations.

The following table sets forth certain operating data as a percentage of revenue for the periods indicated.

	Percentage of Revenue Years Ended	
	FY 2018 December 29, 2018	FY 2017 December 30, 2017
Revenues	100.0 %	100.0 %
Cost of revenues	59.0 %	62.7 %
Gross margin	41.0 %	37.3 %
Operating expenses:		
Research and development	9.4 %	12.5 %
Sales and marketing	39.4 %	35.0 %
General and administrative	22.4 %	21.1 %
Gain on sale of intellectual property	0.0 %	(0.4 %)
Impairment of long-lived assets	0.0 %	0.1 %
Total operating expenses	71.2 %	68.3 %
(Loss) income from operations	(30.2 %)	(31.0 %)
Other (expense) income, net	0.2 %	(0.3 %)
(Loss) income from operations before (benefit from) provision for income taxes	(30.0 %)	(31.2 %)
(Benefit from) provision for income taxes	0.1 %	(0.3 %)
Net (loss) income	(30.1 %)	(30.9 %)

Comparison of 2018 and 2017

Revenues.

Our total revenues increased $1.0 million or 2.4% from $41.6 million in 2017 to $42.6 million in 2018. The increase was due primarily to an increase in our international systems revenues and recurring revenues, partially offset by a decrease in our domestic systems sales. Domestic systems sales were impacted by a decrease in retina system sales primarily due to the impact of our voluntary recall. The increase in international systems revenues was primarily due to an increase in G6 system sales. Our recurring revenues increased due to an increase in G6 related probes sales, partially offset by a decrease in legacy probes sales.

(in millions)	FY 2018	FY 2017	Change in $	Change in %
Systems – domestic	$7.3	$8.0	$ (0.7)	(8.8 %)
Systems – international	12.7	11.7	1.0	8.5 %
Recurring revenues	22.6	21.9	0.7	3.2 %
Total revenues	$42.6	$41.6	$ 1.0	2.4 %

Gross Profit.

Gross profit increased $2.0 million or 12.7% from $15.5 million in 2017 to $17.5 million in 2018. Gross margin increased 3.7 percentage points from 37.3% in 2017 to 41.0% in 2018. Gross margin improved primarily due to lower manufacturing costs and elimination of costs associated with our voluntary LIO product recall in 2017, partially offset by the impact of a shift in geographic mix.

Gross margins are expected to continue to fluctuate due to changes in the relative proportions of domestic and international sales, the product mix of sales, manufacturing variances, total unit volume changes that lead to greater or lesser production efficiencies, sales return and a variety of other factors.

Research and Development.

R&D expenses decreased $1.2 million or 23.1% from $5.2 million in 2017 to $4.0 million in 2018. The decrease was attributable primarily to a decrease in salaries and related costs as a result of decrease in headcount and a decrease in share-based compensation expense.

Sales and Marketing.

Sales and marketing expenses increased $2.2 million or 15.4%, from $14.5 million in 2017 to $16.8 million in 2018. The increase was attributable primarily to an increase in salaries and related costs due to an increase in headcount and an increase in other general selling and marketing expenses.

General and Administrative.

General and administrative expenses increased $0.8 million or 8.8% from $8.8 million in 2017 to $9.6 million in 2018. The increase in spending was attributable primarily to an increase in headcount and associated costs, an increase in our German operations and an increase in legal expense.

Gain on sale of intellectual property

During 2017, we recognized a $0.2 million gain on sale of intellectual property which was written off in 2016.

Other Income (Expense).

Other expense totaled $0.1 million in 2018 and was attributable primarily to interest income, partially offset by an increase in the fair value re-measurement of the contingent earn-out liabilities of the RetinaLabs acquisition. Other expense totaled $0.1 million in 2017 and was attributed primarily to an increase in the fair value re-measurement of the contingent earn-out liabilities of the RetinaLabs acquisition, partially offset by interest income.

Income Taxes.

We recorded a provision for income taxes of $37 thousand for the year ended December 29, 2018 compared to a benefit from income taxes of $0.1 million for the year ended December 30, 2017. The effective tax rate for the year ended December 29, 2018 was negative 0.29% compared to an effective tax rate of 0.98% for the year ended December 30, 2017. The income tax valuation allowance was $15.5 million at the end of 2018 compared to $12.3 million at the end of 2017.

Liquidity and Capital Resources

Liquidity is our ability to generate sufficient cash flows from operating activities to meet our obligations and commitments. In addition, liquidity includes the ability to obtain appropriate financing or to raise capital.

Comparison of 2018 and 2017

As of December 29, 2018, we had cash and cash equivalents of $21.2 million, no debt and working capital of $28.5 million compared to cash and cash equivalents of $21.7 million, no debt and working capital of $29.1 million as of December 30, 2017.

Net cash used in operating activities was $10.0 million in 2018 compared to $3.6 million in 2017. The increase in net cash used in operating activities was primarily due to changes in working capital, driven by lower cash collections, timing of vendor payments and increase in operating expenses.

During 2018, net cash used in investing activities was $0.8 million, which consisted of $0.4 million for capital expenditures and $0.4 million payments of the contingent earn-out liability. Net cash used in investing activities during 2017 was $0.8 million, which consisted of $0.6 million for capital expenditures and $0.4 million for payment

of the contingent earn-out liability, partially offset by $0.2 million proceeds from sale of intellectual property.

During 2018, net cash provided by financing activities was $10.4 million, which consisted of $10.5 million net proceeds arising from the issuance of common stock and $0.1 million proceeds from stock option exercises, partially offset by $0.2 million payroll taxes related to net share settlement of equity awards. Net cash provided by financing activities during 2017 was $2.3 million, which consisted of $2.3 million net proceeds arising from issuance of common stock and $0.4 million proceeds from stock option exercises, partially offset by $0.3 million payroll taxes related to net share settlement of equity awards.

We believe our existing cash and cash equivalents will be sufficient to meet our anticipated cash needs over the next 12 months.

Critical Accounting Policies

Revenue Recognition.

Our revenues arise from the sale of laser consoles, delivery devices, consumables, service, and support activities. We also derive revenue from royalties from third parties which are typically based on licensees' net sales of products that utilize our technology. Our revenue is recognized in accordance with Accounting Standards Codification ("ASC") 606, "Revenue from Contracts with Customers."

The Company has the following revenue transaction types: (1) Product Sale Only, (2) VIP/LAP Programs, (3) Extended Warranty, (4) System Repairs (outside of warranty) and (5) Royalty Revenue.

(1) Product Sale Only: The Company's products consist of laser consoles, delivery devices and consumable instrumentation, including laser probes. The Company's products are currently sold for use by ophthalmologists specializing in the treatment of glaucoma and retinal diseases. Inside the United States and Germany the products are sold directly to the end users. In other countries outside of the United States, the Company utilizes independent, third-party distributors to market and sell the Company's products. There is no continuing obligation subsequent to the shipment to the distributors.

Under the new guidance, there is no change in our revenue recognition for product-sale-only transactions, as compared to revenue recognition for these transactions under the prior revenue recognition standards. The Company recognizes revenue from product sale at a point in time. When a system or disposables are sold without any additional deliverables, the Company recognizes revenue using the five-step model: (1) identifying the contract with the customer, (2) identifying the performance obligations in the contract, (3) determining expected transaction price, (4) allocating the transaction price to the distinct performance obligations in the contract, and (5) recognizing revenue when (or as) the performance obligations are satisfied.

(2) VIP/LAP Programs: The Company sometimes enters into VIP or Laser Advantage Program (LAP) contracts with customers. For the VIP program, under the terms of such contracts, the customer is not charged for the system upon the initial agreement, but rather is obligated to purchase a quarterly minimum quantity of Endoprobes (classified as disposables) at a premium during the contract period, such that at the end of the contract period the system has been paid in full. The Company decided to replace its previously utilized VIP program (contract length of two years) with an LAP program (contract length of 12 months or less) beginning in fourth quarter of 2016. Under the LAP program, the system is given away free of charge and title is transferred after the customer purchases the minimum required number of boxes of probes (classified as disposables). Customers with older machines have the ability to trade in their old machines for the most current laser equipment offered in the program (G6 Laser) and receive a discount on the program's minimum purchase requirements. Under ASC 606, this non-cash consideration must be included in the transaction price. However, the Company has determined that there is no value associated with the old machine and the trade in is essentially offered to encourage customers to purchase more consumables under the program.

Under the new guidance, there is no change in our revenue recognition for product sales under VIP/LAP programs as compared to revenue recognition for these transactions under the prior revenue recognition standards. The Company recognizes revenue from product sales under VIP/LAP programs at a point in time. For both programs, the Company allocates the transaction price of the distinct performance obligations in the contract by determining stand-alone selling price using historical pricing net of any variable consideration or discounts to specifically allocate to a particular performance obligation.

(3) Extended Warranty: The Company offers a standard 2 year warranty on all system sales (5 years on the laser heads for its IQ 532/577 laser consoles). The Company also offers an extended warranty which is sold to customers in incremental, one-year warranty periods which begin subsequent to the expiration of the standard 2 year warranty. The customer can opt to purchase the extended warranty at the time of the system sale or after the initial system sale.

Under the new guidance, there is no change in our revenue recognition for extended warranty as compared to revenue recognition for these transactions under the prior revenue recognition standards. The Company recognizes revenue from extended warranty ratably over the warranty period. Revenue recognition for the sale of an extended warranty is largely dependent on the timing of the sale as follows:

a. Extended Warranty Sale in Conjunction with System Sale: If the customer opts to purchase an extended warranty at the time of the system sale, the Company allocates the transaction price of the distinct performance obligations in the contract by determining stand-alone selling price using historical pricing net of any variable consideration or discounts to specifically allocate to a particular performance obligation.

b. Extended Warranty Sale Subsequent to System Sale: If the customer opts to purchase an extended warranty after the initial system sale, the Company determines the amount of time that has elapsed since the initial system sale. If the extended warranty is purchased within 60 days of the initial sale, the Company considers this sale to be an additional element of the original sale and allocates the transaction price of the distinct performance obligations in the contract by determining stand-alone selling price using historical pricing net of any variable consideration or discounts to specifically allocate to a particular performance obligation. If the extended warranty is purchased subsequent to sixty days after the initial sale, the sale of the extended warranty is deemed a separate contract and is deferred at the selling price and recognized ratably over the extended warranty period as the performance obligation is satisfied.

35

(4) System Repairs (outside of warranty): Customers will sometime request repairs from the Company subsequent to the expiration of the standard warranty and outside of an extended warranty contract.

Under the new guidance, there is no change in our revenue recognition for system repairs (outside warranty) as compared to revenue recognition for these transactions under the prior revenue recognition standards. The Company recognizes revenue from system repairs (outside of warranty) at a point in time. When the customer requests repairs from the Company subsequent to the expiration of the standard warranty and outside of an extended warranty contracts, these repair contracts are considered separate from the initial sale, and as such, revenue is recognized as the repair services are rendered and the performance obligation satisfied.

(5) Royalty Revenue: The Company has royalty agreements with two customers related to the sale of the Company's intellectual property. Under the terms of these agreements, the customer is to remit a percentage of sales to the Company.

Under the new guidance, since these arrangements are for sales-based licenses of intellectual property, for which the guidance in paragraph ASC 606-10-55-65 applies, the Company recognizes revenue only as the subsequent sale occurs. However, the Company notes that such sales being reported by the licensee with a quarter in arrear, such revenue is recognized at the time it is reported and paid by the licensee given that any estimated variable consideration would have to be fully constrained due to the unpredictability of such estimate and the unavoidable risk that it may lead to significant revenue reversals.

The Company elected the practical expedient allowing it to not recognize as a contract asset the commission paid to its salesforce on the sale of its products as an incremental cost of obtaining a contract with a customer but rather recognize such commission as expense when incurred as the amortization period of the asset that the Company would have otherwise recognized is one year or less. There is no change in the Company's accounting for commissions.

Inventories.

Inventories are stated at the lower of cost or net realizable value and include on-hand inventory physically held at our facility, sales demo inventory and service loaner inventory. Cost is determined on a standard cost basis which approximates actual cost on a first-in, first-out ("FIFO") method. Lower of cost or net realizable value is evaluated by considering obsolescence, excessive levels of inventory, deterioration and other factors. Adjustments to reduce the cost of inventory to its net realizable value, if required, are made for estimated excess, obsolete or impaired inventory and are charged to cost of revenues. Once the cost of the inventory is reduced, a new lower-cost basis for that inventory is established, and subsequent changes in facts and circumstances do not result in the restoration or increase in that newly established cost basis. Factors influencing these adjustments include changes in demand, product life cycle and development plans, component cost trends, product pricing, physical deterioration and quality issues. Revisions to these adjustments would be required if these factors differ from our estimates.

Sales Returns Allowance and Allowance for Doubtful Accounts.

We estimate future product returns related to current period product revenue. We analyze historical returns, and changes in customer demand and acceptance of our products when evaluating the adequacy of the sales returns allowance. Significant management judgment and estimates must be made and used in connection with establishing the sales returns allowance in any accounting period. Material differences may result in the amount and timing of our revenue for any period if management made different judgments or utilized different estimates. Our provision for sales returns is recorded net of the associated costs.

Similarly, management must make estimates regarding the uncollectibility of accounts receivable. We are exposed to credit risk in the event of non-payment by customers to the extent of amounts recorded on the consolidated balance sheets. As sales increase the level of accounts receivable would likely also increase. In addition, in the event that customers were to delay their payments to us, the levels of accounts receivable would likely also increase. We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make

required payments. The allowance for doubtful accounts is based on past payment history with the customer, analysis of the customer's current financial condition, the aging of the accounts receivable balance, customer concentration and other known factors.

Warranty.

We provide reserves for the estimated cost of product warranties at the time revenue is recognized based on historical experience of known product failure rates and expected material and labor costs to provide warranty services. We generally provide a two-year warranty on our products. Additionally, from time to time, specific warranty accruals may be made if unforeseen technical problems arise. Alternatively, if estimates are determined to be greater than the actual amounts necessary, we may reverse a portion of such provisions in future periods. Actual warranty costs incurred have not materially differed from those accrued. Our warranty policy is applicable to products which are considered defective in their performance or fail to meet the product specifications. Warranty costs are reflected in the consolidated statements of operations as cost of revenues.

Income Taxes.

We account for income taxes in accordance with ASC 740, “Income Taxes” (“ASC 740”), which requires that deferred tax assets and liabilities be recognized using enacted tax rates for the effect of temporary differences between the book and tax bases of recorded assets and liabilities. Under ASC 740, the liability method is used in accounting for income taxes. Deferred tax assets and liabilities are determined based on the differences between financial reporting and the tax basis of assets and liabilities, and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. ASC 740 also requires that deferred tax assets be reduced by a valuation allowance if it is more likely than not that some or all of the deferred tax asset will not be realized. We annually evaluate the realizability of our deferred tax assets by assessing our valuation allowance and by adjusting the amount of such allowance, if necessary. The factors used to assess the likelihood of realization include our forecast of future taxable income and available tax planning strategies that could be implemented to realize the net deferred tax assets. In 2014, we released the valuation allowance against most of our deferred tax assets except that we retained a valuation allowance for certain deferred tax assets associated with our California research and development credit (“CA R&D credit”). In 2018, based on the Company's recent history of losses and its forecasted losses, management believes on the more likely than not basis that a full valuation allowance is required. Accordingly, in the fourth quarter of fiscal year 2018, the Company provided a full valuation allowance on its federal and states deferred tax assets.

Accounting for Uncertainty in Income Taxes.

We account for uncertain tax positions in accordance with ASC 740. ASC 740 seeks to reduce the diversity in practice associated with certain aspects of measurement and recognition in accounting for income taxes. ASC 740 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax provision that an entity takes or expects to take in a tax return. Additionally, ASC 740 provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosures, and transition. Under ASC 740, an entity may only recognize or continue to recognize tax positions that meet a "more-likely-than-not" threshold. In accordance with our accounting policy, we recognize accrued interest and penalties related to unrecognized tax benefits as a component of income tax expense. There was no accrued interest and penalties during the year ended December 29, 2018.

Accounting for Stock-Based Compensation.

We account for stock-based compensation granted to employees and directors, including employees’ stock option awards, restricted stock and restricted stock units at grant date, based on the fair value of the award. Stock-based compensation is recognized as expense on a ratable basis over the requisite service period of the award.

We value options using the Black-Scholes option pricing model. Restricted stock and time-based restricted stock units are valued at the grant date fair value of the underlying common shares. Performance-based restricted stock units are valued using a Monte Carlo simulation model. The Black-Scholes option pricing model requires the use of highly subjective and complex assumptions which determine the fair value of share-based awards, including the option’s expected term and the price volatility of the underlying stock. The Monte Carlo simulation model incorporates assumptions for the holding period, risk-free interest rate, stock price volatility and dividend yield.

Recently Adopted Accounting Standards.

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-09 Revenue from Contracts with Customers (Topic 606) (“ASC 606”), which, along with amendments issued in 2015, 2016 and 2017, replaces nearly all current U.S. GAAP guidance on this topic with a comprehensive revenue measurement and recognition standard and expanded disclosure requirements. This new guidance provides a five-step analysis in determining when and how revenue is recognized. Under the new guidance, revenue is recognized when a customer obtains control of promised goods or services and is recognized in an amount that reflects the consideration

which the entity expects to receive in exchange for those goods or services. In addition, the new guidance requires disclosure of the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers.

As part of our assessment and implementation plan, we evaluated our policies, procedures and internal controls. In preparation for adoption of the standard, the Company has implemented internal controls to enable the preparation of financial information, including the assessment of the impact of the standard. The Company has adopted this guidance using the modified retrospective method in the first quarter of fiscal 2018. Under the modified retrospective method, the new standards apply to all new contracts initiated on or after the effective date, and for contracts which have remaining obligations as of the effective date, an adjustment to the opening balance of retained earnings is required. Based on the results of the procedures taken in adopting this standard, we determined that our accounting for revenues under the then prescribed standard (ASC 605) was not different from the new ASC 606 standard. As such, we did not have any adjustments to our opening balance of our retained earnings.

In August 2016, the FASB issued ASU 2016-15 “Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments.” The amendment gives guidance and reduces diversity in practice with respect to certain types of cash flows. This ASU is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. An entity that elects early adoption must adopt all of the amendments in the same period. The adoption of this standard in fiscal year 2018 did not have a material impact on our consolidated financial statements.

In October 2016, the FASB issued ASU 2016-16, to ASC 740 “Income Taxes,” which simplifies the recording of an inter-entity transfer of assets other than inventory. The new guidance requires that a company recognize the income tax consequences of an intra-entity transfer of an asset other than inventory when the transfer occurs. The new guidance becomes effective for annual reporting periods beginning after December 15, 2017 and must be applied using a modified retrospective basis through a cumulative-effect adjustment directly to retained earnings as of the beginning of the adoption period. The adoption of this standard in fiscal year 2018 did not have a material impact on the Company’s consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, “Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting.” The amendments in ASU 2017-09 include guidance on determining which changes to the terms and conditions of share-based payment awards require an entity to apply modification accounting under Topic 718. These amendments require the entity to account for the effects of a modification unless all of the following conditions are met: the fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the modified award is the same as the fair value (or value using an alternative measurement method) of the original award immediately before the original award is modified; the vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified; and the classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified. This guidance is effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, with early adoption permitted. The adoption of this standard in fiscal year 2018 did not have a material impact on the Company’s consolidated financial statements.

Recent Accounting Standards Not Yet Adopted.

In February 2016, the FASB issued ASU 2016-02, “Leases,” which, along with subsequent amendments, modified lessee accounting guidance under Topic 840. This ASU requires the Company to recognize on the balance sheet the assets and liabilities for the rights and obligations created by leases with terms of more than twelve months. This ASU also requires disclosures enabling the users of financial statements to understand the amount, timing and uncertainty of cash flows arising from leases. This new standard will become effective for annual periods beginning after December 15, 2018 (including interim reporting periods within those periods). Early adoption is permitted as of the beginning of an interim or annual reporting period. The Company will adopt the new standard in the first quarter of its fiscal year 2019 using the optional transition method. The Company will elect not to reassess whether any expired or existing contracts are or contain leases, not to reassess the lease classification for any expired or existing leases, not to reassess initial direct costs for any existing leases and not to separate non-lease components from lease components and instead account for each separate lease component and the non-lease components associated with that lease component as a single lease component for new or modified leases. While we continue to evaluate certain provisions of the standard, based on our current estimates, we expect the adoption of the standard will result in recognition of right-of-use assets and lease liabilities, primarily relating to real estate operating leases, of approximately $4.0 million and $4.5 million, respectively, as of the first day of fiscal year 2019, on the Company’s consolidated balance sheets. No material impact is expected to the Company’s consolidated statements of operations or its consolidated statements of cash flows.

In August 2018, the FASB issued ASU 2018-13, “Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement,” which removes, modifies and adds certain disclosure requirements on fair value measurements. The new guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted. The Company is currently evaluating the effect of the adoption of this guidance on its consolidated financial statements.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

As a “smaller reporting company,” as defined in Rule 12b-2 of the Exchange Act, we are not required to provide the information called for by this Item.

Item 8. Financial Statements and Supplementary Data.

Our consolidated balance sheets as of December 29, 2018 and December 30, 2017 and the consolidated statements of operations, comprehensive income, stockholders’ equity and cash flows for each of our fiscal years 2018 and 2017 together with the related notes and the report of our independent registered public accounting firm, are on the following pages. Additional required financial information is described in Item 15.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of IRIDEX Corporation

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of IRIDEX Corporation (a Delaware corporation) and its subsidiaries (the "Company") as of December 29, 2018 and December 30, 2017, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the two years in the period ended December 29, 2018, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 29, 2018 and December 30, 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 29, 2018, in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Principle

As discussed in Note 1 to the consolidated financial statements, the Company changed its method of accounting for revenues from contracts with customers in 2018 due to the adoption of the new revenue standard.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BPM LLP

We have served as the Company's auditor since 2007.

San Jose, California

March 29, 2019

IRIDEX Corporation

CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share data)

	FY 2018 December 29, 2018	FY 2017 December 30, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 21,194	$ 21,707
Accounts receivable, net of allowance for doubtful accounts of $213 as of December 29, 2018 and $226 as of December 30, 2017	9,083	7,863
Inventories	8,794	9,381
Prepaid expenses and other current assets	547	500
Total current assets	39,618	39,451
Property and equipment, net	1,220	1,403
Intangible assets, net	100	116
Goodwill	533	533
Other long-term assets	201	143
Total assets	$ 41,672	$ 41,646
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,516	$ 1,724
Accrued compensation	2,962	2,459
Accrued expenses	2,763	2,153
Accrued warranty	622	1,536
Deferred revenue	2,225	2,520
Total current liabilities	11,088	10,392
Long-term liabilities:		
Accrued warranty	238	199
Other long-term liabilities	385	533
Total liabilities	11,711	11,124
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $0.01 par value, 2,000,000 shares authorized, no shares issued and outstanding	—	—
Common stock, $0.01 par value:		
Authorized: 30,000,000 shares;		
Issued and outstanding 13,602,052 and 11,596,274 shares as of December 29, 2018 and December 30, 2017, respectively	145	126
Additional paid-in capital	71,548	59,385
Accumulated other comprehensive income	70	—
Accumulated deficit	(41,802)	(28,989)
Total stockholders' equity	29,961	30,522
Total liabilities and stockholders' equity	$ 41,672	$ 41,646

The accompanying notes are an integral part of these consolidated financial statements.

IRIDEX Corporation

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

	FY 2018 Year Ended December 29, 2018	FY 2017 Year Ended December 30, 2017
Total revenues	$ 42,600	$ 41,593
Cost of revenues	25,129	26,090
Gross profit	17,471	15,503
Operating expenses:		
Research and development	4,006	5,208
Sales and marketing	16,782	14,541
General and administrative	9,551	8,782
Gain on sale of intellectual property	—	(175)
Impairment of long-lived assets	—	35
Total operating expenses	30,339	28,391
Loss from operations	(12,868)	(12,888)
Other income (expense), net	92	(107)
Loss from operations before provision for (benefit from) income taxes	(12,776)	(12,995)
Provision for (benefit from) income taxes	37	(128)
Net loss	$ (12,813)	$ (12,867)
Net loss per share:		
Basic	$ (1.05)	$ (1.11)
Diluted	$ (1.05)	$ (1.11)
Weighted average shares used in computing net loss per common share:		
Basic	12,199	11,555
Diluted	12,199	11,555

The accompanying notes are an integral part of these consolidated financial statements.

IRIDEX Corporation

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

	FY 2018 Year Ended December 29, 2018	FY 2017 Year Ended December 30, 2017
Net loss	$ (12,813)	$ (12,867)
Change in foreign currency translation adjustments	70	—
Comprehensive loss	$ (12,743)	$ (12,867)

The accompanying notes are an integral part of these consolidated financial statements.

IRIDEX Corporation

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in thousands, except share data)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive Income	Accumulated	
	Shares	Amount	Capital	(Loss)	Deficit	Total
FY 2016: Balances, December 31, 2016	11,304,736	$ 124	$ 55,158	$ —	$ (16,122)	$ 39,160
Proceeds from issuance of common stock, net of issuance costs	172,500	2	2,261			2,263
Issuance of common stock under stock option plan	64,380		377			377
Employee stock-based compensation expense			1,922			1,922
Release of restricted stock	54,658		(333)			(333)
Net loss					(12,867)	(12,867)
FY 2017: Balances, December 30, 2017	11,596,274	126	59,385	—	(28,989)	30,522
Proceeds from issuance of common stock, net of issuance costs	1,916,667	19	10,456			10,475
Issuance of common stock under stock option plan	24,050		98			98
Employee stock-based compensation expense			1,803			1,803
Release of restricted stock	65,061		(194)			(194)
Other comprehensive income				70		70
Net loss					(12,813)	(12,813)
FY 2018: Balances, December 29, 2018	13,602,052	$ 145	$ 71,548	$ 70	$ (41,802)	$ 29,961

The accompanying notes are an integral part of these consolidated financial statements.

IRIDEX Corporation

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	FY 2018 Year Ended December 29, 2018	FY 2017 Year Ended December 30, 2017
Operating activities:		
Net loss	$ (12,813)	$ (12,867)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on sale of intellectual property	—	(175)
Impairment of long-lived assets	—	35
Loss on disposal of property and equipment	4	—
Depreciation and amortization	809	858
Change in fair value of earn-out liability	149	260
Stock-based compensation	1,803	1,922
Changes in operating assets and liabilities:		
Accounts receivable	(1,159)	2,162
Inventories	463	2,091
Prepaid expenses and other current assets	(54)	(50)
Other long-term assets	(49)	(63)
Accounts payable	788	(270)
Accrued compensation	503	113
Accrued expenses	614	25
Accrued warranty	(875)	1,132
Deferred revenue	(295)	1,137
Other long-term liabilities	87	125
Net cash used in operating activities	(10,025)	(3,565)
Investing activities:		
Acquisition of property and equipment	(440)	(575)
Proceeds from sale of intellectual property	—	175
Payment on earn-out liability	(387)	(382)
Net cash used in investing activities	(827)	(782)
Financing activities:		
Proceeds from issuance of common stock, net of issuance costs	10,475	2,263
Proceeds from stock option exercises	98	377
Taxes paid related to net share settlements of equity awards	(194)	(333)
Net cash provided by financing activities	10,379	2,307
Effect of foreign exchange rate changes	(40)	—
Net decrease in cash and cash equivalents	(513)	(2,040)
Cash and cash equivalents, beginning of year	21,707	23,747
Cash and cash equivalents, end of year	$ 21,194	$ 21,707
Supplemental disclosure of cash flow information:		
Cash paid during the year for:		
Income taxes	$ 13	$ 7

Supplemental disclosure of non-cash activities:		
Transfer of inventory to property and equipment	$ 166	$ 171

The accompanying notes are an integral part of these consolidated financial statements.

IRIDEX Corporation

Notes to Consolidated Financial Statements

1. Organization

Description of Business.

IRIDEX Corporation ("IRIDEX", the "Company", "we", "us", or "our") is a leading worldwide provider of therapeutic based laser systems, delivery devices and consumable instrumentation used to treat sight-threatening eye diseases in ophthalmology. Our ophthalmology products are sold in the United States and Germany predominantly through a direct sales force and internationally through independent distributors.

2. Summary of Significant Accounting Policies

Financial Statement Presentation.

The consolidated financial statements include the accounts of IRIDEX and our wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

Our fiscal year always ends on the Saturday closest to December 31. Fiscal 2018 ended on December 29, 2018 ("FY 2018") and Fiscal 2017 ended on December 30, 2017 ("FY 2017"). Fiscal years 2018 and 2017 each included 52 weeks of operations.

Use of Estimates.

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, and expenses and the related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates. In addition, any change in these estimates or their related assumptions could have an adverse effect on our operating results.

Cash and Cash Equivalents.

We consider all highly liquid debt instruments with insignificant interest rate risk and an original maturity of three months or less when purchased to be cash equivalents. Cash equivalents consist primarily of cash deposits in money market funds that are available for withdrawal without restriction.

Sales Returns Allowance and Allowance for Doubtful Accounts.

We estimate future product returns related to current period product revenue. We analyze historical returns, and changes in customer demand and acceptance of our products when evaluating the adequacy of the sales returns allowance. Significant management judgment and estimates must be made and used in connection with establishing the sales returns allowance in any accounting period. Material differences may result in the amount and timing of our revenue for any period if management made different judgments or utilized different estimates. Our provision for sales returns is recorded net of the associated costs. The balance for the provision for sales returns was $277 thousand and $570 thousand as of December 29, 2018 and December 30, 2017, respectively, and is recorded within the deferred

revenue accounts in the consolidated balance sheets.

Similarly management must make estimates regarding the uncollectibility of accounts receivable. We are exposed to credit risk in the event of non-payment by customers to the extent of amounts recorded on the consolidated balance sheets. As sales levels change, the level of accounts receivable would likely also change. In addition, in the event that customers were to delay their payments to us, the levels of accounts receivable would likely increase. We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. The allowance for doubtful accounts is based on past payment history with the customer, analysis of the customer's current financial condition, the aging of the accounts receivable balance, customer concentration and other known factors.

A reconciliation of the changes in our allowance for doubtful accounts balances for the years ended December 29, 2018 and December 30, 2017 are as follows (in thousands):

Description	Balance at Beginning of The period	Additions	(Deductions)	Balance at End of The period
Allowance for doubtful accounts Years ended				
December 29, 2018	226	31	(44)	213
December 30, 2017	230	24	(28)	226

Inventories.

Inventories are stated at the lower of cost or net realizable value and include on-hand inventory physically held at our facility, sales demo inventory and service loaner inventory. Cost is determined on a standard cost basis which approximates actual cost on a first-in, first-out (“FIFO”) method. Lower of cost or net realizable value is evaluated by considering obsolescence, excessive levels of inventory, deterioration and other factors. Adjustments to reduce the cost of inventory to its net realizable value, if required, are made for estimated excess, obsolescence or impaired inventory and are charged to cost of revenues. Once the cost of the inventory is reduced, a new lower-cost basis for that inventory is established, and subsequent changes in facts and circumstances do not result in the restoration or increase in that newly established cost basis. Factors influencing these adjustments include changes in demand, product life cycle and development plans, component cost trends, product pricing, physical deterioration and quality issues. Revisions to these adjustments would be required if these factors differ from our estimates.

As part of our normal business, we generally utilize various finished goods inventory as either sales demos to facilitate the sale of our products to prospective customers, or as loaners that we allow our existing customers to use while we repair their products. We are amortizing these demos and loaners over an estimated useful life of four years. The amortization of the demos is charged to sales and marketing expense while the amortization on the loaners is charged to cost of revenues. The gross value of demos and loaners was $3.1 million and $2.4 million, and the accumulated amortization was $1.4 million and $0.9 million as of December 29, 2018 and December 30, 2017, respectively. The net book value of demos and loaners is charged to cost of revenues when such demos or loaners are sold.

Property and Equipment.

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization are calculated on a straight–line basis over the estimated useful lives of the assets, which is generally three years. Leasehold improvements are amortized over the lesser of their estimated useful lives or the lease term. Repairs and maintenance costs are expensed as incurred.

Valuation of Goodwill and Intangible Assets.

Goodwill represents the excess of the purchase price over the fair value of the net tangible and identifiable intangible assets acquired in a business combination. The Company reviews goodwill for impairment on an annual basis or whenever events or changes in circumstances indicate the carrying value may not be recoverable. The Company performs an annual impairment test by comparing the fair value of a reporting unit with its carrying amount. An impairment charge should be recognized for the amount by which the carrying amount exceeds the reporting unit’s fair

value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. In addition, income tax effects from any tax deductible goodwill carrying amount of the reporting unit should be considered when measuring the goodwill impairment loss, if applicable. The Company has determined that it has a single reporting unit for purposes of performing its goodwill impairment test. As the Company uses the market approach to assess impairment, its common stock price is an important component of the fair value calculation. If the Company's stock price continues to experience significant price and volume fluctuations, this will impact the fair value of the reporting unit and can lead to potential impairment in future periods. The Company performed its annual impairment test during the second quarter of fiscal 2018 and determined that its goodwill was not impaired. As of December 29, 2018, we had not identified any factors that indicated there was an impairment of our goodwill and determined that no additional impairment analysis was then required.

Intangible assets with definite lives are amortized over the useful life of the asset. We review our amortizing intangible assets for impairment whenever events or changes in circumstances indicate that their carrying value may not be recoverable. An asset is considered impaired if its carrying amount exceeds the future non-discounted net cash flow the asset is expected to generate. If an asset is considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds its fair value. In such circumstances, we conduct an impairment analysis in accordance with Accounting Standard Codification ("ASC") 350, "Intangibles – Goodwill and Other" ("ASC 350").

Revenue Recognition.

Our revenues arise from the sale of laser consoles, delivery devices, consumables, service, and support activities. We also derive revenue from royalties from third parties which are typically based on licensees' net sales of products that utilize our technology. Our revenue is recognized in accordance with Accounting Standards Codification ("ASC") 606, "Revenue from Contracts with Customers."

The Company has the following revenue transaction types: (1) Product Sale Only, (2) VIP/LAP Programs, (3) Extended Warranty, (4) System Repairs (outside of warranty) and (5) Royalty Revenue.

(1) Product Sale Only: The Company's products consist of laser consoles, delivery devices and consumable instrumentation, including laser probes. The Company's products are currently sold for use by ophthalmologists specializing in the treatment of glaucoma and retinal diseases. Inside the United States and Germany the products are sold directly to the end users. In other countries outside of the United States, the Company utilizes independent, third-party distributors to market and sell the Company's products. There is no continuing obligation subsequent to the shipment to the distributors.

Under the new guidance, there is no change in our revenue recognition for product-sale-only transactions, as compared to revenue recognition for these transactions under the prior revenue recognition standards. The Company recognizes revenue from product sale at a point in time. When a system or disposables are sold without any additional deliverables, the Company recognizes revenue using the five-step model: (1) identifying the contract with the customer, (2) identifying the performance obligations in the contract, (3) determining expected transaction price, (4) allocating the transaction price to the distinct performance obligations in the contract, and (5) recognizing revenue when (or as) the performance obligations are satisfied.

(2) VIP/LAP Programs: The Company sometimes enters into VIP or Laser Advantage Program (LAP) contracts with customers. For the VIP program, under the terms of such contracts, the customer is not charged for the system upon the initial agreement, but rather is obligated to purchase a quarterly minimum quantity of Endoprobes (classified as disposables) at a premium during the contract period, such that at the end of the contract period the system has been paid in full. The Company decided to replace its previously utilized VIP program (contract length of two years) with an LAP program (contract length of 12 months or less) beginning in fourth quarter of 2016. Under the LAP program, the system is given away free of charge and title is transferred after the customer purchases the minimum required number of boxes of probes (classified as disposables). Customers with older machines have the ability to trade in their old machines for the most current laser equipment offered in the program (G6 Laser) and receive a discount on the program's minimum purchase requirements. Under ASC 606, this non-cash consideration must be included in the transaction price. However, the Company has determined that there is no value associated with the old machine and the trade in is essentially offered to encourage customers to purchase more consumables under the program.

Under the new guidance, there is no change in our revenue recognition for product sales under VIP/LAP programs as compared to revenue recognition for these transactions under the prior revenue recognition standards. The Company recognizes revenue from product sales under VIP/LAP programs at a point in time. For both programs, the Company allocates the transaction price of the distinct performance obligations in the contract by determining stand-alone selling price using historical pricing net of any variable consideration or discounts to specifically allocate to a particular performance obligation.

(3) Extended Warranty: The Company offers a standard 2-year warranty on all system sales (5 years on the laser heads for its IQ 532/577 laser consoles). The Company also offers an extended warranty which is sold to customers in incremental, one-year warranty periods which begin subsequent to the expiration of the standard 2-year warranty. The customer can opt to purchase the extended warranty at the time of the system sale or after the initial system sale.

Under the new guidance, there is no change in our revenue recognition for extended warranty as compared to revenue recognition for these transactions under the prior revenue recognition standards. The Company recognizes revenue

from extended warranty ratably over the warranty period. Revenue recognition for the sale of an extended warranty is largely dependent on the timing of the sale as follows:

a. Extended Warranty Sale in Conjunction with System Sale: If the customer opts to purchase an extended warranty at the time of the system sale, the Company allocates the transaction price of the distinct performance obligations in the contract by determining stand-alone selling price using historical pricing net of any variable consideration or discounts to specifically allocate to a particular performance obligation.

b. Extended Warranty Sale Subsequent to System Sale: If the customer opts to purchase an extended warranty after the initial system sale, the Company determines the amount of time that has elapsed since the initial system sale. If the extended warranty is purchased within 60 days of the initial sale, the Company considers this sale to be an additional element of the original sale and allocates the transaction price of the distinct performance obligations in the contract by determining stand-alone selling price using historical pricing net of any variable consideration or discounts to specifically allocate to a particular performance obligation. If the extended warranty is purchased subsequent to sixty days after the initial sale, the sale of the extended warranty is deemed a separate contract and is deferred at the selling price and recognized ratably over the extended warranty period as the performance obligation is satisfied.

(4) System Repairs (outside of warranty): Customers will sometime request repairs from the Company subsequent to the expiration of the standard warranty and outside of an extended warranty contract.

Under the new guidance, there is no change in our revenue recognition for system repairs (outside warranty) as compared to revenue recognition for these transactions under the prior revenue recognition standards. The Company recognizes revenue from system repairs (outside of warranty) at a point in time. When the customer requests repairs from the Company subsequent to the expiration of the standard warranty and outside of an extended warranty contracts, these repair contracts are considered separate from the initial sale, and as such, revenue is recognized as the repair services are rendered and the performance obligation satisfied.

(5) Royalty Revenue: The Company has royalty agreements with two customers related to the sale of the Company's intellectual property. Under the terms of these agreements, the customer is to remit a percentage of sales to the Company.

Under the new guidance, since these arrangements are for sales-based licenses of intellectual property, for which the guidance in paragraph ASC 606-10-55-65 applies, the Company recognizes revenue only as the subsequent sale occurs. However, the Company notes that such sales being reported by the licensee with a quarter in arrear, such revenue is recognized at the time it is reported and paid by the licensee given that any estimated variable consideration would have to be fully constrained due to the unpredictability of such estimate and the unavoidable risk that it may lead to significant revenue reversals.

The Company elected the practical expedient allowing it to not recognize as a contract asset the commission paid to its salesforce on the sale of its products as an incremental cost of obtaining a contract with a customer but rather recognize such commission as expense when incurred as the amortization period of the asset that the Company would have otherwise recognized is one year or less. There is no change in the Company's accounting for commissions.

Taxes Collected from Customers and Remitted to Governmental Authorities.

Taxes collected from customers and remitted to governmental authorities are recognized on a net basis in the accompanying consolidated statements of operations as well as accrued expenses to the degree which is appropriate.

Deferred Revenue.

Deferred revenue represents contract liabilities. Revenue related to extended service contracts is deferred and recognized on a straight-line basis over the period of the applicable service period. Costs associated with these service arrangements are recognized as incurred. Approximately $1.6 million of the deferred revenue balance is expected to be recognized over the next 12 months.

A reconciliation of the changes in our deferred revenue balances for the years ended December 29, 2018 and December 30, 2017 are as follows (in thousands):

FY 2016: Balance as of December 31, 2016	$1,383

Additions to deferral	2,451
Revenue recognized	(1,314)
FY 2017: Balance as of December 30, 2017	2,520
Additions to deferral	1,984
Revenue recognized	(2,279)
FY 2018: Balance as of December 29, 2018	$2,225

Warranty.

We provide reserves for the estimated cost of product warranties at the time revenue is recognized based on historical experience of known product failure rates and expected material and labor costs to provide warranty services. We generally provide a two-year warranty on our products. In March 2017, the Company began offering a 5 year warranty on the laser heads for its IQ 532/577 laser consoles. Actual warranty costs incurred have not materially differed from those accrued. The Company's warranty policy is applicable to products which are considered defective in their performance or fail to meet the product specifications. Additionally, from time to time, specific warranty accruals may be made if unforeseen technical problems arise. If estimates are determined to be greater than the actual amounts necessary, we may reverse a portion of such provisions in future periods. Warranty costs are reflected in the consolidated statements of operations as costs of revenues.

A reconciliation of the changes in our warranty liability for the years ended December 29, 2018 and December 30, 2017 are as follows (in thousands):

FY 2016: Balance as of December 31, 2016	$603
Accruals for product warranties	1,476
Cost of warranty claims	(344)
FY 2017: Balance as of December 30, 2017	1,735
Accruals for product warranties	454
Cost of warranty claims	(1,329)
FY 2018: Balance as of December 29, 2018	$860

Shipping and Handling Costs.

Our shipping and handling costs billed to customers are included in revenues and the associated expense is recorded in cost of revenues for all periods presented. Shipping and handling costs billed to customers amounted to $0.3 million for each of the fiscal years 2018 and 2017.

Research and Development.

Research and development expenditures are charged to operations as incurred.

Advertising.

Advertising and promotion costs are expensed as they are incurred; such costs were approximately $0.5 million in 2018 and $0.2 million in 2017 and are included in sales and marketing expenses in the accompanying consolidated statements of operations.

Income Taxes.

We account for income taxes in accordance with ASC 740, "Income Taxes" ("ASC 740"), which requires that deferred tax assets and liabilities be recognized using enacted tax rates for the effect of temporary differences between the book and tax bases of recorded assets and liabilities. Under ASC 740, the liability method is used in accounting for income taxes. Deferred tax assets and liabilities are determined based on the differences between financial reporting and the tax basis of assets and liabilities, and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. ASC 740 also requires that deferred tax assets be reduced by a valuation allowance if it is more likely than not that some or all of the deferred tax asset will not be realized. We annually

evaluate the realizability of our deferred tax assets by assessing our valuation allowance and by adjusting the amount of such allowance, if necessary. The factors used to assess the likelihood of realization include our forecast of future taxable income and available tax planning strategies that could be implemented to realize the net deferred tax assets. In 2014, we released valuation allowance against most of our deferred tax assets except that we retained a valuation allowance for certain deferred tax assets associated with our California research and development credit ("CA R&D credit"). In 2018, based on the Company's recent history of losses and its forecasted losses, management believes on the more likely than not basis that a full valuation allowance is required. Accordingly, in the fourth quarter of fiscal year 2018, the Company provided a full valuation allowance on its federal and states deferred tax assets.

Accounting for Uncertainty in Income Taxes.

We account for uncertain tax positions in accordance with ASC 740. ASC 740 seeks to reduce the diversity in practice associated with certain aspects of measurement and recognition in accounting for income taxes. ASC 740 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax provision that an entity takes or expects to take in a tax return. Additionally, ASC 740 provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosures, and transition. Under ASC 740, an entity may only recognize or continue to recognize tax positions that meet a "more-likely-than-not" threshold. In accordance with our accounting policy, we recognize accrued interest and penalties related to unrecognized tax benefits as a component of income tax expense. There were no accrued interest and penalties during the years ended December 29, 2018 and December 30, 2017.

Accounting for Stock-Based Compensation.

The Company accounts for stock-based compensation granted to employees and directors, including employees stock option awards, restricted stock and restricted stock units in accordance with ASC 718, “Compensation – Stock Compensation” (“ASC 718”). Accordingly, stock-based compensation cost is measured at grant date, based on the fair value of the award, and is recognized as expense over the employee’s service period. The Company recognizes compensation expense on a ratable basis over the requisite service period of the award.

The Company values options using the Black-Scholes option pricing model. Restricted stock and time-based restricted stock units are valued at the grant date fair value of the underlying common shares. Performance-based restricted stock units with market conditions are valued using the Monte Carlo simulation model. The Black-Scholes option pricing model requires the use of highly subjective and complex assumptions which determine the fair value of stock-based awards, including the option’s expected term and the price volatility of the underlying stock. The Monte Carlo simulation model incorporates assumptions for the holding period, risk-free interest rate, stock price volatility and dividend yield.

Concentration of Credit Risk and Other Risks and Uncertainties.

Our cash and cash equivalents are deposited in demand and money market accounts. Deposits held with banks may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and therefore, bear minimal risk.

We market our products to distributors and end-users throughout the world. Sales to international distributors are generally made on open credit terms and letters of credit. Management performs ongoing credit evaluations of our customers and maintains an allowance for potential credit losses. Historically, we have not experienced any significant losses related to individual customers or a group of customers in any particular geographic area. For the years ended December 29, 2018 and December 30, 2017, no single customer accounted for greater than 10% of total revenues. As of December 29, 2018 and December 30, 2017, no customer accounted for more than 10% of accounts receivable balance.

Our products require approvals from the Food and Drug Administration and international regulatory agencies prior to commercialized sales. Our future products may not receive required approvals. If we were denied such approvals, or if such approvals were delayed, it would have a materially adverse impact on our business, results of operations and financial condition.

Reliance on Certain Suppliers.

Certain components and services used to manufacture and develop our products are presently available from only one or a limited number of suppliers or vendors. The loss of any of these suppliers or vendors would potentially require a

significant level of hardware and/or software development efforts to incorporate the products or services into our products.

Net Income per Share.

Basic net income per share is based upon the weighted average number of common shares outstanding during the period. Diluted net income per share is based upon the weighted average number of common shares outstanding and dilutive common stock equivalents outstanding during the period. Common stock equivalents consist of incremental common shares issuable upon the exercise of stock options and release (vesting) of restricted stock units and awards and are calculated under the treasury stock method. Common stock equivalent shares from unexercised stock options and unvested restricted stock units are excluded from the computation for periods in which we incur a net loss or if the exercise price of such options is greater than the average market price of our common stock for the period as their effect would be anti-dilutive. See Note 15 - Computation of Basic and Diluted Net Income Per Common Share.

Reclassifications

Certain reclassifications have been made to the prior year statements included in these consolidated financial statements to conform to the current year presentation. The reclassifications had no impact on previously reported net loss or accumulated deficit.

Recently Adopted Accounting Standards.

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-09 Revenue from Contracts with Customers (Topic 606) ("ASC 606"), which, along with amendments issued in 2015, 2016 and 2017, replaces nearly all current U.S. GAAP guidance on this topic with a comprehensive revenue measurement and recognition standard and expanded disclosure requirements. This new guidance provides a five-step analysis in determining when and how revenue is recognized. Under the new guidance, revenue is recognized when a customer obtains control of promised goods or services and is recognized in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. In addition, the new guidance requires disclosure of the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers.

As part of our assessment and implementation plan, we evaluated our policies, procedures and internal controls. In preparation for adoption of the standard, the Company has implemented internal controls to enable the preparation of financial information, including the assessment of the impact of the standard. The Company has adopted this guidance using the modified retrospective method in the first quarter of fiscal 2018. Under the modified retrospective method, the new standards apply to all new contracts initiated on or after the effective date, and for contracts which have remaining obligations as of the effective date, an adjustment to the opening balance of retained earnings is required. Based on the results of the procedures taken in adopting this standard, we determined that our accounting for revenues under the then prescribed standard (ASC 605) was not different from the new ASC 606 standard. As such, we did not have any adjustments to our opening balance of our retained earnings.

In August 2016, the FASB issued ASU 2016-15 "Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments." The amendment gives guidance and reduces diversity in practice with respect to certain types of cash flows. This ASU is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. If an entity early adopts the amendments in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. An entity that elects early adoption must adopt all of the amendments in the same period. The adoption of this standard in fiscal year 2018 did not have a material impact on our consolidated financial statements.

In October 2016, the FASB issued ASU 2016-16, to ASC 740 "Income Taxes," which simplifies the recording of an inter-entity transfer of assets other than inventory. The new guidance requires that a company recognize the income tax consequences of an intra-entity transfer of an asset other than inventory when the transfer occurs. The new guidance becomes effective for annual reporting periods beginning after December 15, 2017 and must be applied using a modified retrospective basis through a cumulative-effect adjustment directly to retained earnings as of the beginning of the adoption period. The adoption of this standard in fiscal year 2018 did not have a material impact on the Company's consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, "Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting." The amendments in ASU 2017-09 include guidance on determining which changes to the terms and conditions of share-based payment awards require an entity to apply modification accounting under Topic 718. These amendments require the entity to account for the effects of a modification unless all of the following conditions are met: the fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the modified award is the same as the fair value (or value using an alternative measurement method) of the

original award immediately before the original award is modified; the vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified; and the classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified. This guidance is effective for annual reporting periods beginning after December 15, 2017, including interim periods within that reporting period, with early adoption permitted. The adoption of this standard in fiscal year 2018 did not have a material impact on the Company’s consolidated financial statements.

Recent Accounting Standards Not Yet Adopted.

In February 2016, the FASB issued ASU 2016-02, “Leases,” which, along with subsequent amendments, modified lessee accounting guidance under Topic 840. This ASU requires the Company to recognize on the balance sheet the assets and liabilities for the rights and obligations created by leases with terms of more than twelve months. This ASU also requires disclosures enabling the users of financial statements to understand the amount, timing and uncertainty of cash flows arising from leases. This new standard will become effective for annual periods beginning after December 15, 2018 (including interim reporting periods within those periods). Early adoption is permitted as of the beginning of an interim or annual reporting period. The Company will adopt the new standard in the first quarter of its fiscal year 2019 using the optional transition method. The Company will elect not to reassess whether any expired or existing contracts are or contain leases, not to reassess the lease classification for any expired or existing leases, not to reassess initial direct costs for any existing leases and not to separate non-lease components from lease components and instead account for each separate lease component and the non-lease components associated with that lease component as a single lease component for new or modified leases. While we continue to evaluate certain provisions of the standard, based on our current estimates, we expect the adoption of the standard will result in recognition of right-of-use assets and lease liabilities, primarily relating to real estate operating leases, of approximately $4.0 million and $4.5 million, respectively, as of the first day of fiscal year 2019, on the Company’s consolidated balance sheets. No material impact is expected to the Company’s consolidated statements of operations or its consolidated statements of cash flows.

In August 2018, the FASB issued ASU 2018-13, “Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement,” which removes, modifies and adds certain disclosure requirements on fair value measurements. The new guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted. The Company is currently evaluating the effect of the adoption of this guidance on its consolidated financial statements.

3. Fair Value Measurement

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value hierarchy distinguishes between (1) market participant assumptions developed based on market data obtained from independent sources (observable inputs) and (2) an entity’s own assumptions about market participant assumptions developed based on the best information available in the circumstances (unobservable inputs). The fair value hierarchy consists of three broad levels, which gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). The three levels of the fair value hierarchy are described below:

- Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities.
- Level 2: Directly or indirectly observable inputs as of the reporting date through correlation with market data, including quoted prices for similar assets and liabilities in active markets and quoted prices in markets that are not active. Level 2 also includes assets and liabilities that are valued using models or other pricing methodologies that do not require significant judgment since the input assumptions used in the models, such as interest rates and volatility factors, are corroborated by readily observable data from actively quoted markets for substantially the full term of the financial instrument.
- Level 3: Unobservable inputs that are supported by little or no market activity and reflect the use of significant management judgment. These values are generally determined using pricing models for which the assumptions utilize management’s estimates of market participant assumptions.

In determining fair value, we utilize valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in our assessment of fair value.

The carrying amounts of our financial assets and liabilities, including cash and cash equivalents, accounts receivable, accounts payable, and accrued expenses as of December 29, 2018 and December 30, 2017, approximate fair value because of the short maturity of these instruments.

As of December 29, 2018 and December 30, 2017, financial assets and liabilities measured and recognized at fair value on a recurring basis and classified under the appropriate level of the fair value hierarchy as described above was as follows (in thousands):

	As of December 29, 2018 Fair Value Measurements				As of December 30, 2017 Fair Value Measurements			
(in thousands)	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Money market funds	$20,708	$ —	$—	$20,708	$20,950	$ —	$—	$20,950
Liabilities:								
Earn-out liability	$—	$ —	$334	$334	$—	$ —	$572	$572

The Company's Level 1 financial assets are money market funds whose fair values are based on quoted market prices. The Company does not have any Level 2 financial assets or liabilities. The fair value of the earn-out liability arising from the acquisition of RetinaLabs, Inc. is classified within Level 3 of the fair value hierarchy since it is based on significant unobservable inputs. The significant unobservable inputs include projected royalties and discount rates to present value the payments. A significant increase (decrease) in the projected royalty payments in isolation could result in a significantly higher (lower) fair value measurement and a significant increase (decrease) in the discount rate in isolation could result in a significantly lower (higher) fair value measurement. The fair value of the earn-out liability is calculated on a quarterly basis by the Company based on a collaborative effort of the Company's operations, finance and accounting groups as additional information becomes available. Any change in the fair value adjustment is recorded in the statement of operations of that period. The decrease in re-measurement of the contingent earn-out was due to a decrease in expected future revenues to be generated from these acquisitions. The deal was structured with an earn-out component. The earn-out liability is included in accrued expenses and other long-term liabilities in the consolidated balance sheets.

Charges related to fair value adjustments for the earn-out liability were $149 thousand and $260 thousand for the fiscal years 2018 and 2017, respectively.

The following table presents quantitative information about the inputs and valuation methodologies used for our fair value measurements classified in Level 3 of the fair value hierarchy as of December 29, 2018 and December 30, 2017.

As of December 29, 2018	Fair Value (in thousands)	Valuation Technique	Significant Unobservable Input	Weighted Average (range)
Earn-out liability	$ 334	Discounted cash flow	Projected royalties (in thousands)	$1,245
			Discount rate	10.33% (10.20% - 27.00%)

As of December 30, 2017	Fair Value (in thousands)	Valuation Technique	Significant Unobservable	Weighted Average

			Input	(range)
Earn-out liability	$ 572	Discounted cash flow	Projected royalties (in thousands)	$1,622
			Discount rate	10.90% (10.90% - 27.00%)

The following table provides a reconciliation of the beginning and ending balances of the contingent consideration – cash (Level 3 liabilities) (in thousands):

Balance as of December 31, 2016	$694
Payments against earn-out	(382)
Change in fair value of earn-out liability	260
Balance as of December 30, 2017	572
Payments against earn-out	(387)
Change in fair value of earn-out liability	149
Balance as of December 29, 2018	$334

4. Inventories

The components of our inventories are as follows (in thousands):

	FY 2018 December 29, 2018	FY 2017 December 30, 2017
Raw materials	$ 2,675	$ 4,147
Work in process	1,075	1,278
Finished goods	5,044	3,956
Total inventories	$ 8,794	$ 9,381

5. Property and Equipment

The components of our property and equipment are as follows (in thousands):

	FY 2018 December 29, 2018	FY 2017 December 30, 2017
Equipment	$ 10,502	$ 10,088
Leasehold improvements	2,516	2,364
Less: accumulated depreciation and amortization	(11,798)	(11,049)
Property and equipment, net	$ 1,220	$ 1,403

Depreciation expense related to property and equipment was $793 thousand and $842 thousand for the fiscal years 2018 and 2017, respectively.

6. Goodwill

The carrying value of goodwill was $533 thousand as of December 29, 2018 and December 30, 2017, respectively.

Goodwill is tested for impairment at least annually or whenever there is a change in circumstances that indicates the carrying value of these assets may be impaired. The determination of whether any potential impairment of goodwill exists is based upon an impairment test performed in accordance with ASC 350. There was no impairment of goodwill recognized during fiscal years 2018 and 2017.

7. Intangible Assets

The components of our purchased intangible assets as of December 29, 2018 are as follows (in thousands):

	Useful	FY 2018	Gross	Accumulated	Net	Useful Lives

	Lives	Annual Amortization	Carrying Value	Amortization	Carrying Value	Remaining
Customer relations	15 Years	$ 16	$ 240	$ 140	$ 100	6.25 Years
Patents	Varies	—	600	600	—	Varies
		$ 16	$ 840	$ 740	$ 100	

The components of our purchased intangible assets as of December 30, 2017 are as follows (in thousands):

	Useful Lives	FY 2017 Annual Amortization	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Useful Lives Remaining
Customer relations	15 Years	$ 16	$ 240	$ 124	$ 116	7.25 Years
Patents	Varies	—	600	600	—	Varies
		$ 16	$ 840	$ 724	$ 116	

Aggregate amortization expense for each of the fiscal years 2018 and 2017 was $16 thousand. The amortization of customer relations was charged to sales and marketing expense and the amortization of patents was charged to cost of revenues.

Estimated future amortization expense for purchased intangible assets is as follows (in thousands):

Fiscal Year:	
2019	$16
2020	16
2021	16
2022	16
2023	16
Thereafter	20
Total	$100

8. Accrued Expenses

The components of our accrued expenses are as follows (in thousands):

	FY 2018 December 29, 2018	FY 2017 December 30, 2017
Customer deposits	$ 671	$ 509
Earn-out – short term	334	337
Distributor commission	291	293
Sales and use tax payable	26	57
Royalties payable	84	82
Deferred rent	131	—
Other accrued expenses	1,226	875
Total accrued expenses	$ 2,763	$ 2,153

9. Commitments and Contingencies

Lease Agreements.

We lease our operating facilities in Mountain View, California, under a non-cancelable operating lease through February 28, 2022. There are no remaining options to extend or renew the terms of this lease. Rent expense for fiscal years 2018 and 2017 was approximately $1.2 million and $1.1 million, respectively.

Our operating lease commitments consist of facility and office equipment leases. Future minimum lease payments under current operating leases as of December 29, 2018 are summarized as follows (in thousands):

Fiscal Year	Operating Lease Payments
2019	$ 1,430

2020	1,509
2021	1,495
2022	310
2023	—
Total future minimum lease payments	$ 4,744

Manufacture and Supply Agreement.

Future minimum payments for manufacture and supply commitments as of December 29, 2018 are summarized as follows (in thousands):

Fiscal Year	Contract Manufacturing and Supply Commitments
2019	$ 9,035
2020	1,407
Total contract manufacturing and supply commitments	$ 10,442

License Agreements.

We are obligated to pay royalties equivalent to 5% of sales on certain products under certain license agreements with termination dates as early as the end of 2018 and as late as the end of 2021. Royalty expense, charged to cost of revenues, was approximately $0.3 million for each of the fiscal years 2018 and 2017.

Indemnification Arrangements.

We enter into standard indemnification arrangements in our ordinary course of business. Pursuant to these arrangements, we indemnify, hold harmless, and agree to reimburse the indemnified parties for losses suffered or incurred by the indemnified parties (generally our business partners or customers) in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third-party with respect to our products. The term of these indemnification agreements is generally perpetual any time after the execution of the agreement. The maximum potential amount of future payments we could be required to make under these agreements is not determinable. We have never incurred costs to defend lawsuits or settle claims related to these indemnification agreements. As a result, we believe the estimated fair value of these agreements is minimal.

We have entered into indemnification agreements with our directors and officers that may require us to indemnify our directors and officers against liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct of a culpable nature. These agreements also require us to advance their expenses incurred as a result of any proceeding against them as to which they could be indemnified and to make good faith determination whether or not it is practicable for us to obtain directors and officers insurance. We currently have directors and officers liability insurance.

Legal Proceedings.

In January 2018, we filed a lawsuit against Quantel Medical, S.A., Quantel USA, Inc., and Quantel, S.A. (collectively, “Quantel”) in the U.S. District Court for the Northern District of California. The lawsuit alleges that Quantel products infringe U.S. Patent No. 7,771,417, that Quantel breached an earlier agreement between Quantel and the Company, and that Quantel has infringed upon the Company’s MicroPulse® trademark, Registration No. 4550188 on the principal register. Quantel previously had a limited license to the asserted Company patent and trademark. Our complaint filed in connection with this matter asserts that the license was terminated in early 2017 for material breach, but that Quantel continued to use our intellectual property without authorization.

In March 2017, OD-OS GmbH noticed an opposition to the Company’s European Patent No. currently EP 1 856 774 at the European Patent Office (“EPO”). On June 8, 2018, Quantel intervened in the Opposition. Oral proceedings on the opposition took place on July 13, 2018. At the conclusion of those proceedings, the EPO’s Opposition Division communicated that it would move to revoke the patent. The formal written decision from the Opposition Division was issued on October 1, 2018. The Company filed its notice of appeal on October 10, 2018.

In late May of 2018, Quantel applied to the Paris District Court in Paris, France for a ruling that its products do not infringe the French Part of Iridex’s European Patent at issue in the opposition, EP 1 856 774.

On February 12, 2019, we announced the resolution of our dispute with Quantel and dismissed the lawsuit we filed against Quantel in the U.S. District Court for the Northern District of California. Quantel dismissed and ceased its participation in parallel proceedings against us in Europe.

In addition, from time to time, we may be involved in legal proceedings arising in the ordinary course of business.

In general, management believes that claims which are pending or known to be threatened, will not have a material adverse effect on our financial position or results of operations and are adequately covered by our liability insurance.

However, it is possible that cash flows or results of operations could be materially affected in any particular period by the unfavorable resolution of one of more of these contingencies or because of the diversion of management's attention and the incurrence of significant expenses.

10. Stockholders' Equity

1998 Stock Plan.

The 1998 Stock Plan (the "1998 Plan"), as amended, provides for the granting to employees (including officers and non-employee directors) of incentive stock options and for the granting to employees (including officers and non-employee directors) and consultants of nonstatutory stock options, stock purchase rights ("SPRs"), restricted stock, restricted stock units ("RSUs"), performance shares, performance units and stock appreciation rights. The exercise price of incentive stock options and stock appreciation rights granted under the 1998 Plan must be at least equal to the fair market value of the shares at the time of grant. With respect to any recipient who owns stock possessing more than 10% of the voting power of our

outstanding capital stock, the exercise price of any option or SPR granted must be at least equal to 110% of the fair market value at the time of grant. Options granted under the 1998 Plan are exercisable at such times and under such conditions as determined by the administrator; generally over a four year period. The maximum term of incentive stock options granted to any recipient must not exceed ten years; provided, however, that the maximum term of an incentive stock option granted to any recipient possessing more than 10% of the voting power of our outstanding capital stock must not exceed five years. In the case of SPRs, unless the administrator determines otherwise, we have a repurchase option exercisable upon the voluntary or involuntary termination of the purchaser's employment with us for any reason (including death or disability). Such repurchase option lapses at a rate determined by the administrator. The purchase price for shares repurchased is the original price paid by the purchaser. The form of consideration for exercising an option or stock purchase right, including the method of payment, is determined by the administrator. The 1998 Plan expired in February 2008.

2008 Equity Incentive Plan.

On June 11, 2008, the shareholders approved the adoption of the 2008 Equity Incentive Plan, (the "Incentive Plan"). There are no material changes in the Incentive Plan from the 1998 Plan. In 2014, the stockholders approved an amendment to the Incentive Plan for purposes of complying with Section 162(m) of the Internal Revenue Code of 1986, as amended, to increase the share reserve under the Incentive Plan, and to make certain other amendments to the terms of the Incentive Plan. The maximum aggregate number of shares that may be awarded and sold under the Incentive Plan is 2,850,000 shares plus any shares subject to stock options or similar awards granted under the 1998 Plan that expire or otherwise terminate without having been exercised in full and shares issued pursuant to awards granted under the 1998 Plan that are forfeited to us on or after February 23, 2008, which was the date the 1998 Plan expired.

The following table represents the shares activity and the total number of shares available for grant under the Incentive Plan:

	Shares Available for Grant
Balances as of December 31, 2016	162,155
Additional shares reserved	650,000
Options granted	(524,400)
Restricted stock granted	(212,538)
Options cancelled	73,694
Awards cancelled	48,059
Balances as of December 30, 2017	196,970
Additional shares reserved	1,000,000
Options granted	(178,435)
Restricted stock granted	(628,125)
Options cancelled	166,798
Awards cancelled	143,754
Balances as of December 29, 2018	700,962

Awards (RSU, PSU, RSA) with a per share or unit purchase price lower than 100% of the fair market value of the Company's common stock on the date of grant under the 2008 Equity Incentive Plan, as amended, are counted against shares authorized under the plan as one and one-half shares of common stock for each share. When cancelled, these shares are added back to the Plan as one and one-half shares.

The following table shows stock-based compensation expenses by functional area in the consolidated statements of operations for 2018 and 2017(in thousands):

	FY 2018 Year Ended December 29, 2018	FY 2017 Year Ended December 30, 2017
Cost of revenues	$ 47	$ 152
Research and development	129	354
Sales and marketing	448	307
General and administrative	1,179	1,109
Total stock-based compensation expense	$ 1,803	$ 1,922

Stock-based compensation expense capitalized to inventory was immaterial for 2018 and 2017.

As of December 29, 2018, there was $4.8 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements under the Incentive Plan. The cost is expected to be recognized over a weighted average period of 2.38 years.

Summary of Stock Options

The following table summarizes information regarding activity in our stock option plans during the fiscal years ended 2018 and 2017 (in thousands except share and per share data):

	Outstanding Options	
	Number of Shares	Weighted Average Exercise Price
Balances as of December 31, 2016	470,985	8.69
Options granted	524,400	9.90
Options exercised	(64,380)	5.86
Options cancelled or forfeited	(73,694)	10.47
Balances as of December 30, 2017	857,311	$ 9.49
Options granted	178,435	6.00
Options exercised	(24,050)	4.09
Options cancelled or forfeited	(166,798)	9.85
Balances as of December 29, 2018	844,898	$ 8.84

The following table summarizes information with respect to stock options outstanding and exercisable as of December 29, 2018:

	Options Outstanding			Options Vested and Exercisable	
Range of Exercise Prices	Number of Shares Outstanding	Weighted Average Remaining Contractual Life (years)	Weighted Average Exercise Price	Number of Shares Exercisable	Weighted Average Exercise Price
$3.49 - $5.69	99,341	4.77	$ 5.03	37,966	$ 4.37
$5.81 - $6.00	89,926	5.28	$ 5.93	25,390	$ 5.91
$6.30 - $8.47	85,912	3.85	$ 7.24	50,582	$ 7.23

$8.58 - $9.05	85,874	4.11	$ 8.83	55,959	$ 8.71
$9.34 - $9.40	11,875	1.40	$ 9.36	11,875	$ 9.36
$9.54 - $9.54	324,854	5.08	$ 9.54	135,188	$ 9.54
$10.14 - $11.16	83,853	3.81	$ 10.80	65,004	$ 10.75
$12.85 - $12.85	15,394	4.70	$ 12.85	8,520	$ 12.85
$14.61 - $14.61	25,000	5.19	$ 14.61	10,939	$ 14.61
$16.29 - $16.29	22,869	3.18	$ 16.29	16,893	$ 16.29
$3.49 - $16.29	844,898	4.61	$ 8.84	418,316	$ 9.12

The determination of the fair value of options granted is computed using the Black-Scholes option pricing model with the following weighted average assumptions:

	Employee Stock Option Plan	
	FY 2018	FY 2017
Average risk free interest rate	2.69%	1.83 %
Expected life (in years)	4.55 years	4.55 years
Dividend yield	—	—
Average volatility	40.9%	41.8 %

The weighted average grant date fair value of options granted as calculated using the Black-Scholes option pricing was $2.27 and $3.68 per share for the fiscal years 2018 and 2017, respectively.

Option pricing models require the input of various subjective assumptions, including the option’s expected life and the price volatility of the underlying stock. The expected stock price volatility is based on analysis of our stock price history over

a period commensurate with the expected term of the options, trading volume of our stock, look-back volatilities and Company specific events that affected volatility in a prior period. The expected term of employee stock options represents the weighted average period the stock options are expected to remain outstanding and is based on the history of exercises and cancellations on all past option grants made, the contractual term, the vesting period and the expected remaining term of the outstanding options. The risk-free interest rate is based on the U.S. Treasury interest rates whose term is consistent with the expected life of the stock options. No dividend yield is included as we have not issued any dividends and does not anticipate issuing any dividends in the future.

Information regarding stock options outstanding, exercisable and expected to vest as of December 29, 2018 is summarized below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value (thousands)
Options outstanding	844,898	$ 8.84	4.61	$ 12
Options vested and expected to vest	797,921	$ 8.87	4.53	$ 12
Options exercisable	418,316	$ 9.12	3.38	$ 12

The aggregate intrinsic value in the table above represents the total pretax intrinsic value (the difference between our closing stock price on the last trading day of fiscal 2018 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on December 29, 2018. This amount is subject to change due to changes to the fair market value of our common stock. The total intrinsic value of options exercised for fiscal years 2018 and 2017 was approximately $0.1 million and $0.3 million, respectively.

Restricted Stock Awards/Restricted Stock Units

Effective for the 2018 fiscal year and thereafter, each non-employee member of the Board of Directors received an annual equity award of either restricted stock or RSU, at the election of such Board member, in each case equal to $40 thousand worth of our common stock (determined at the fair market value of the shares at the time such award is granted) under our Incentive Plan. Each equity award or RSU vests in full on the one-year anniversary of the date of grant provided that the non-employee member continues to serve on the Board through such date.

Summary of Restricted Stock Units and Awards

We recognize the estimated compensation expense of restricted stock units and awards, net of estimated forfeitures, over the vesting term. The estimated compensation expense is based on the fair value of our common stock on the date of grant.

Information regarding the restricted stock units outstanding, vested and expected to vest as of December 29, 2018 is summarized below:

	Number of Shares	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value (thousands)
Restricted stock units outstanding	597,121	1.44	$ 2,657
Restricted stock units vested and expected to vest	492,239	1.33	$ 2,190

The intrinsic value of the restricted stock units is calculated based on the closing price of our shares as quoted on the Nasdaq Global Market on the last trading day of the fiscal year, December 28, 2018, of $4.45.

The majority of the restricted stock units that were released in fiscal year 2018 were net-share settled such that we withheld shares with value equivalent to the employees' minimum statutory obligation for the applicable income and other employment taxes, and remitted the cash to the appropriate taxing authorities. The total shares withheld were based on the value of the restricted stock units on their release date as determined by our closing stock price. These net-share settlements had the effect of share repurchases as they reduced and retired the number of shares that would have otherwise been issued as a result of the release and did not represent an expense to us. For the fiscal year ended December 29, 2018, 86,941 shares of restricted stock units were released with an intrinsic value of approximately $0.6 million. We withheld 26,181 shares to satisfy approximately $194 thousand of employees' minimum tax obligation on the released restricted stock units.

Information regarding the RSU activity during the years ended December 29, 2018 and December 30, 2017 is summarized below:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding as of December 31, 2016	335,805	$ 11.20
Restricted stock units granted	137,391	$ 9.88
Restricted stock units released	(80,009)	$ 12.37
Restricted stock units forfeited	(32,039)	$ 11.44
Outstanding as of December 30, 2017	361,148	$ 10.42
Restricted stock units granted	418,750	$ 7.79
Restricted stock units released	(86,941)	$ 7.38
Restricted stock units forfeited	(95,836)	$ 10.01
Outstanding as of December 29, 2018	597,121	$ 9.08

During the year ended December 29, 2018, the Company awarded 418,750 restricted stock units at a weighted average grant date fair value of $7.79 per share. Of this amount, 238,200 stock units represent performance-based shares that are subject to service, performance or market vesting conditions with a weighted average grant date fair value of $7.89 per share.

RSUs granted with market conditions are valued using a Monte Carlo simulation model and compensation expense is recognized ratably during the service period even if the market condition is not satisfied. To the extent that the market condition is not met, the RSUs will not vest and will be cancelled.

RSUs granted with performance conditions are valued at the grant date fair value of the underlying common shares. The Company makes a determination regarding the probability of the performance criteria being achieved and compensation expense is recognized ratably over the requisite service period, if it is expected that the performance criteria will be met.

Information regarding the restricted stock awards activity during the year ended December 29, 2018 and December 30, 2017 is summarized below:

	Number of Shares	Weighted Average Grant Date Fair Value

Outstanding as of December 31, 2016	1,289	$ 15.51
Restricted stock awards granted	4,301	$ 9.30
Restricted stock awards released	(1,289)	$ 15.51
Outstanding as of December 30, 2017	4,301	$ 9.30
Restricted stock awards granted	—	—
Restricted stock awards released	(4,301)	$ 9.30
Outstanding as of December 29, 2018	—	—

11. Employee Benefit Plan

We have a plan known as the Iridex Corporation Profit Sharing/401(k) Plan to provide retirement benefits through the deferred salary deductions for substantially all U.S. employees. Employees may contribute up to 15% of their annual compensation to the plan, limited to a maximum amount set by the Internal Revenue Service. The plan also provides for Company contributions at the discretion of the Board of Directors. In 2018 and 2017, total matching contributions made by the Company were $233 thousand and $248 thousand, respectively.

12. Income Taxes

Loss from operations before provision for (benefit from) income taxes was comprised of the following:

	FY 2018 Year Ended December 29, 2018	FY 2017 Year Ended December 30, 2017
United States	$ (12,671)	$ (12,800)
Foreign	(105)	(195)
Total	$ (12,776)	$ (12,995)

The provision for (benefit from) income taxes includes:

	FY 2018 Year Ended December 29, 2018	FY 2017 Year Ended December 30, 2017
Current:		
Federal	$ —	$ (90)
State	26	16
Foreign	9	—
	35	(74)
Deferred:		
Federal	1	(55)
State	1	1
	2	(54)
Provision for (benefit from) income taxes	$ 37	$ (128)

Our effective tax rate differs from the statutory federal income tax rate as shown in the following schedule:

	FY 2018 Year Ended December 29, 2018	FY 2017 Year Ended December 30, 2017
Income tax provision at statutory rate	21.0%	34.0%
State income taxes, net of federal benefit	2.7%	2.4%
Permanent differences	(0.4)%	(0.0)%
Research and development credits	0.1%	0.6%
Change in valuation allowance	(24.8)%	(32.5)%

Foreign rate differential	(0.2	)%	(0.5	)%
Other	1.3	%	(3.0	)%
Effective tax rate	(0.3	)%	1.0	%

The tax effect of temporary differences and carryforwards that give rise to significant portions of the net deferred tax assets are presented below (in thousands):

	FY 2018 Year Ended December 29, 2018	FY 2017 Year Ended December 30, 2017
Net operating losses	$ 8,195	$ 5,757
Research and development credits	3,048	2,839
Accruals and reserves	2,357	2,031
Deferred revenue	304	341
Property and equipment	314	314
Intangible assets	452	495
Stock compensation	797	528
Other tax credits	1	1
Net deferred tax asset	15,468	12,306
Valuation allowance	(15,485)	(12,320)
Net deferred tax liabilities	$ (17)	$ (14)

Our accounting for deferred taxes involves the evaluation of a number of factors concerning the realizability of our deferred tax assets. Assessing the realizability of deferred tax assets is dependent upon several factors, including the likelihood and amount, if any, of future taxable income in relevant jurisdictions during the periods in which those temporary differences become deductible. Our management forecasts taxable income by considering all available positive and negative evidence including our history of operating income or losses and our financial plans and estimates which are used to manage the business. These assumptions require significant judgment about future taxable income. The amount of deferred tax assets considered realizable is subject to adjustment in future periods if estimates of future taxable income are reduced.

As of December 29, 2018, based on the Company's recent history of losses and its forecasted losses, management believes on the more likely than not basis that a full valuation allowance is required. Accordingly, in the fourth quarter of fiscal year 2018, the Company provided a full valuation allowance on its federal and state deferred tax assets. As of December 29, 2018, the Company had federal and state net operating loss (“NOL”) carry forwards of $32.3 million and $21.1 million respectively. The federal NOL will begin to expire in 2033 and the state NOL will begin to expire in 2021.

The Company has federal and state research credit carry forwards of approximately $1.9 million and $2.7 million, respectively, available to and development credits are subject to IRC sections 382 and 383. In the event of a change in ownership as defined by these code sections, the usage of the above mentioned NOL’s and credits may be limited.

The comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the “Tax Act”) was enacted in the United States on December 22, 2017 and includes, among other items, a reduction in the federal corporate income tax rate from 35% to 21%, certain interest expense deduction limitations and changes in the timing of certain taxable income. We are required to recognize the effect of the tax law changes in the period of enactment, such as remeasuring our U.S. deferred tax assets and liabilities and reassessing the net realizability of our deferred tax assets and liabilities.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118 (“SAB 118”) which provides guidance on accounting for the tax effects of the Tax Act. We have completed our analysis and accounting with respect the Tax Act and identified no additional changes from amounts previously recorded. However, changes in law, interpretations, and facts may result in adjustments to these amounts. Based on the Company’s net operating loss carryovers and valuation allowance, there is no impact to its consolidated financial statements as a result of the accounting for the tax effects of the Tax Act.

The Company accounts for uncertain tax positions in accordance with ASC 740, Income Taxes. ASC 740 seeks to reduce the diversity in practice associated with certain aspects of measurement and recognition in accounting for income taxes. ASC 740 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax provision that an entity takes or expects to take in a tax return. Additionally, ASC 740 provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosures, and transition. Under ASC 740, an entity may only recognize or continue to recognize tax positions that meet a "more likely than not" threshold. In accordance with our accounting policy, we recognize accrued interests and penalties related to unrecognized tax benefits as a component of income tax expense. There is no accrued interest and penalty during the year ended December 29, 2018.

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

	FY 2018 Year Ended December 29, 2018	FY 2017 Year Ended December 30, 2017
Balance at the beginning of the year	$ 1,105	$ 1,029
Additions based upon tax positions related to the current year	35	73
Additions based upon tax positions related to the prior year	15	3
Balance at the end of the year	$ 1,155	$ 1,105

If the ending balance of $1.2 million of unrecognized tax benefits at December 29, 2018 were recognized, $0 of the recognition would affect the income tax rate. The Company does not anticipate any material change in our unrecognized tax benefits over the next twelve months. The unrecognized tax benefits may change during the next year for items that arise in the ordinary course of business.

The Company files U.S. federal and state returns. The tax years 2011 to 2017 remain open in several jurisdictions, none of which have individual significance.

13. Loan and Security Agreement

In November 2016, the Company entered into a Loan and Security Agreement (“Loan Agreement”) with Silicon Valley Bank providing for a $15.0 million secured revolving loan facility (“Revolving Loan Facility”), with availability subject to an accounts receivable borrowing base formula. Borrowings under the Revolving Loan Facility accrue interest at a per annum rate equal to the Wall Street Journal Prime Rate as in effect from time to time, plus 1.5%. The Loan Agreement does not include any financial covenants. The Company may borrow, repay and reborrow funds under the Revolving Loan Facility until November 2, 2019, at which time the Revolving Loan Facility matures and all outstanding amounts must be repaid. As of December 29, 2018 and December 30, 2017, there were no amounts outstanding.

14. Business Segments and Geographical Information

We operate in one segment, ophthalmology. We develop, manufacture and market medical devices. Our revenues arise from the sale of consoles, delivery devices, consumables, service and support activities.

Revenue information shown by product is as follows (in thousands):

	FY 2018 Year Ended December 29, 2018	FY 2017 Year Ended December 30, 2017
Systems	$ 20,009	$ 19,703

Recurring revenues(1)	22,591	21,890
Total revenues	$ 42,600	$ 41,593

(1) Include service contract revenues of $1,318 and $1,160 recognized during fiscal years 2018 and 2017, respectively. Service contract revenues are recognized ratably over the service contract period.

Revenue information shown by geographic region is as follows (in thousands):

	FY 2018 Year Ended December 29, 2018	FY 2017 Year Ended December 30, 2017
United States	$ 22,097	$ 23,017
Europe	9,742	8,097
Americas, excluding the U.S.	2,590	2,319
Asia/Pacific Rim	8,171	8,160
	$ 42,600	$ 41,593

Revenues are attributed to countries based on location of end customers. For fiscal years 2018 and 2017 no individual country accounted for more than 10% of our sales, except for the United States, which accounted for 51.9% and 55.3% of revenues in 2018 and 2017, respectively.

15. Computation of Basic and Diluted Net Loss Per Common Share

A reconciliation of the numerator and denominator of basic and diluted net income per common share is provided as follows (in thousands, except per share amounts):

	FY 2018 Year Ended December 29, 2018	FY 2017 Year Ended December 30, 2017
Numerator:		
Net loss	$ (12,813)	$ (12,867)
Denominator:		
Weighted average shares of common stock (basic)	12,199	11,555
Weighted average shares of common stock (diluted)	12,199	11,555
Per share data:		
Basic net (loss) income per share	$ (1.05)	$ (1.11)
Diluted net (loss) income per share	$ (1.05)	$ (1.11)

As of December 29, 2018 and December 30, 2017, stock options, restricted stock units and restricted stock awards of 1,196,352 and 837,269 shares, respectively, were excluded from the computation of diluted weighted average shares outstanding because to do so would have been anti-dilutive.

16. Subsequent Events

The Company has evaluated subsequent events and has concluded that no subsequent events that require disclosure in the financial statements have occurred since the fiscal year ended December 29, 2018.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

Not applicable.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

Our management, with the participation of our Principal Executive and Financial Officer and Principal Accounting Officer, evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15 under the Exchange Act. In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Based on management's evaluation, our Principal Executive and Financial Officer and Principal Accounting Officer concluded that, as of December 29, 2018, our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Principal Executive and Financial Officer and Principal Accounting Officer, as appropriate, to allow timely decisions regarding required disclosure.

Management's Report on Internal Control over Financial Reporting.

Our management is responsible for establishing and maintaining adequate internal control over the company's financial reporting. There are inherent limitations in the effectiveness of any internal control, including the possibility of human error and the circumvention or overriding of controls. Accordingly, even any effective internal control can provide only reasonable assurance with respect to financial statement preparation. Further, because of changes in conditions, the effectiveness of any internal control may vary over time. Our management assessed the effectiveness of the company's internal control over financial reporting as of December 29, 2018. In making this assessment, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013). Based on our assessment using those criteria, our management concluded that, as of December 29, 2018, our internal control over financial reporting is effective.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report is not subject to attestation by our independent registered public accounting firm.

Changes in Internal Control over Financial Reporting.

There were no changes in our internal control over financial reporting that occurred during the fourth quarter of fiscal year 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting, as defined in Rule 13a-15(f) and 15(d)-15(f) under the Exchange Act.

Inherent Limitations on Effectiveness of Controls

Our management, including our Principal Executive and Financial Officer and Principal Accounting Officer, believes that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more persons or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Item 9B. Other Information

Not applicable.

PART III

Certain information required by Part III has been omitted from this Form 10-K. This information is instead incorporated herein by reference to our definitive Proxy Statement, which we will file within 120 days after the end of our fiscal year pursuant to Regulation 14A in time for our Annual Meeting of Stockholders to be held in 2019.

Item 10. Directors, Executive Officers and Corporate Governance

Information regarding our directors is incorporated herein by reference to “Proposal One - Election of Directors - Nominees” in our Proxy Statement. The information concerning our current executive officers is incorporated herein by reference to “Executive Officers” in our Proxy Statement. Information regarding delinquent filers is incorporated by reference to “Section 16(a) Beneficial Ownership Reporting Compliance” in our Proxy Statement. Information regarding our code of business conduct and ethics is incorporated herein by reference to “Corporate Governance Matters - Code of Business Conduct and Ethics” in our Proxy Statement.

Item 11. Executive Compensation

The information required by this item is incorporated herein by reference to “Executive Compensation” in our Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this Item is incorporated herein by reference to “Security Ownership of Certain Beneficial Owners and Management” in our Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item is incorporated herein by reference to “Certain Relationships and Related Transactions” in our Proxy Statement.

Item 14. Principal Accountant Fees and Services.

The information required by this item is incorporated herein by reference to “Proposal Two - Ratification of the Appointment of Independent Registered Public Accounting Firm” in our Proxy Statement.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) The following documents are filed in Part II of this Annual Report on Form 10-K:

2. Financial Statement Schedule

Schedules have been omitted because they are either not required, not applicable, or the required information is included in the consolidated financial statements or notes thereto.

3. Exhibits

Exhibit Index

Exhibits	Exhibit Title
2.1(13)	Asset Purchase Agreement by and among Cutera, Inc., Registrant, and U.S. Bank, National Association, as Escrow Agent, dated December 30, 2011.
3.1(1) (P)	

	Amended and Restated Certificate of Incorporation of Registrant.
3.2	Amended and Restated Bylaws of Registrant.
4.1(3)	Certificate of Designation, Preferences and Rights of Series A Preferred Stock.
4.2(3)	Investor Rights Agreement, dated as of August 31, 2007, by and among the Registrant, BlueLine Capital Partners, LP; BlueLine Capital Partners III, LP and BlueLine Capital Partners II, LP.
4.3(4)	Amendment No. 1 to Investor Rights Agreement, dated as of March 31, 2009.
4.4(21)	Form of senior indenture, to be entered into between the Registrant and the trustee designated therein.
4.5(21)	Form of senior note with

	respect to each particular series of senior notes.
4.6(21)	Form of subordinated indenture to be entered into between the Registrant and the trustee designated therein.
4.7(21)	Form of subordinated note with respect to each particular series of subordinated notes.
4.8(21)	Form of warrant with respect to each warrant.
4.9(21)	Certificate of designation, preferences and rights with respect to any preferred stock.
4.10(21)	Form of Depositary Agreement with respect to the depositary shares.
4.11(21)	Form of Subscription Agreement.
4.12(21)	Form of Unit with respect to any contractual units.
10.1(18)	Fourth Amendment to

	Lease Agreement dated February 9, 2016 by and between Zappettini Investment Co. and the Registrant.
10.2(20)	Form of Indemnification Agreement with directors and officers.

Exhibits	Exhibit Title
10.3(5)	Lease Agreement dated December 6, 1996 by and between Zappettini Investment Co. and the Registrant, as amended pursuant to Amendment No. 1 dated September 15, 2003 and Amendment No. 2 dated December 22, 2008.
10.3.1(14)	Third Amendment to Lease Agreement dated August 4, 2014 by and between Zappettini Investment Co. and the Registrant.
10.3.2(23)	Fourth Amendment to Lease Agreement dated January 31, 2016 by and between ZIC 12112 Terra Bella LLC and the Registrant.
10.3.3(24)	Triple Net Lease dated April 26, 2017 by and between ZIC 12112 Terra Bella LLC and the Registrant.
10.6(8)*	2005 Employee Stock Purchase Plan.
10.7(9)*	2008 Equity Incentive Plan.
10.8(10)*	Form of 2008 Equity Incentive Plan Option Agreement.
10.9(11)*	Form of Stand-alone stock option agreement.
10.10(3)	Securities Purchase Agreement, dated August 31, 2007, by and among BlueLine Capital Partners, LP, BlueLine Capital Partners III, LP, BlueLine Capital Partners II, LP and the Registrant.
10.11(12)*	Form of 2008 Equity Incentive Plan Restricted Stock Award Agreement.
10.12(12)*	Form of 2008 Equity Incentive Plan Restricted Stock Unit Award Agreement.
10.13(13)*	Restricted Stock Unit Award Agreement granted to William M. Moore under the Company's 2008 Equity Incentive Plan, as amended.
10.14(16)*	Restricted Stock Unit Award Agreement granted to William M. Moore under the Company's 2008 Equity Incentive Plan, as amended.
10.15(17)*	Change in Control Severance Agreement dated March 30, 2015, between the Registrant and William M. Moore.
10.16(19)*	Change in Control Severance Agreement dated as of December 6, 2017 by and between the Company and George Marcellino
10.17(20)*	Offer Letter between the Company and Mr. Mokari effective as of May 13, 2016.
10.18(20)*	Change in Control Severance Agreement, between the Company and Mr. Mokari
10.19(22)	Loan and Security Agreement, dated as of November 2, 2016, between IRIDEX Corporation and Silicon Valley Bank.
21.1 (1) (P)	Subsidiaries of Registrant

23.1	Consent of BPM LLP, Independent Registered Public Accounting Firm.
24.1	Power of Attorney (included on signature page).
31.1	Certification of Principal Executive and Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Accounting Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Principal Executive and Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Accounting Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.

Exhibits	Exhibit Title
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

*Indicates a management contract or compensatory plan or arrangement.
(1) Incorporated by reference to the Exhibits filed with the Registration Statement on Form SB-2 (No. 333-00320-LA) which was declared effective on February 15, 1996.
(3) Incorporated by reference to the Exhibits filed with the Registrant's Report on Form 8-K on September 7, 2007.
(4) Incorporated by reference to the Exhibits filed with the Registrant's Report on Form 8-K on April 6, 2009.
(5) Incorporated by reference to the Exhibits filed with the Registrant's Report on Form 10-K for the year ended January 3, 2009.
(8) Incorporated by reference to the appendix filed with the Registrant's Proxy Statement for the Registrant's 2004 Annual Meeting of Stockholders which was filed on April 30, 2004.
(9) Incorporated by reference to the appendix filed with the Registrant's Proxy Statement for the Registrant's 2008 Annual Meeting of Stockholders which was filed on April 24, 2008.
(10) Incorporated by reference to Exhibit 99.1 filed with Registrant's Registration Statement on Form S-8 on November 21, 2008.
(11) Incorporated by reference to Exhibit 99.(d)(5) filed with the Registration Statement on Form SC TO-I July 30, 2009.
(12) Incorporated by reference to the Exhibits filed with the Registrant's Report on Form 10-Q for the quarter ended July 2, 2011.
(13) Incorporated by reference to the Exhibit 10.1 filed with the Registrant's Report on Form 8-K on March 27, 2013.
(14) Incorporated by reference to the Exhibit 2.1 filed with the Registrant's Report on Form 8-K on January 4, 2012.
(15) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Report on Form 10-Q on November 3, 2014.
(16) Incorporated by reference to the Exhibit 10.1 filed with the Registrant's Report on Form 8-K on January 9, 2014.
(17) Incorporated by reference to the Exhibits filed with the Registrant's Report on Form 10-Q on May 12, 2015.
(18) Incorporated by reference to the Exhibit 10.1 filed with the Registrant's Report on Form 10-K on March 31, 2016.
(19) Incorporated by reference to the Exhibit 10.1 filed with the Registrant's Report on Form 8-K on December 6, 2017.
(20) Incorporated by reference to the Exhibits filed with the Registrant's Report on Form 8-K on July 11, 2016,
(21) If applicable, to be filed by amendment to the S-3 (No. 333-213094) which was declared effective on August 26, 2016, or as an exhibit to a report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and incorporated by reference therein.
(22) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Report on Form 8-K on November 3, 2016.
(23) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Report on Form 10-K on March 31, 2016.
(24) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Report on Form 8-K on May 1, 2017.
(P) Print filing.

Trademark Acknowledgments

IRIDEX, the IRIDEX logo, IRIS Medical, MicroPulse, OcuLight, SmartKey, and EndoProbe, are our registered trademarks. G-Probe, DioPexy, DioVet, TruFocus, TrueCW, IQ 577, IQ 532, Cyclo G6, TxCell, OtoProbe, Symphony, EasyFit, Endoview, MoistAir and GreenTip product names are our trademarks. All other trademarks or trade names appearing in this Annual Report on Form 10-K are the property of their respective owners.

69

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Mountain View, State of California, on the 29th day of March 2019.

IRIDEX CORPORATION

By: /s/ William M. Moore
William M. Moore
President and Chief Executive Officer

/s/ Romeo R. Dizon
Romeo R. Dizon
Vice President and Controller

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints William M. Moore, and Romeo Dizon, jointly and severally, their attorney-in-fact, each with full power of substitution, for him in any and all capacities, to sign on behalf of the undersigned any amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, and each of the undersigned does hereby ratifying and confirming all that each of said attorneys-in-fact, or his substitutes, may do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ William M. Moore (William M. Moore)	President, Chief Executive Officer, and Chairman of the Board (Principal Executive and Financial Officer)	March 29, 2019
/s/ Romeo R. Dizon (Romeo R. Dizon)	Vice President and Controller (Principal Accounting Officer)	March 29, 2019
/s/ David I. Bruce (David I. Bruce)	Director	March 29, 2019
/s/ Sanford Fitch (Sanford Fitch)	Director	March 29, 2019
/s/ Robert E. Grove (Robert E. Grove)	Director	March 29, 2019
/s/ Ruediger Naumann-Etienne (Ruediger Naumann-Etienne)	Director	March 29, 2019

/s/ (Maria Sainz) (Maria Sainz)	Director	March 29, 2019