IRIDEX CORP
Form 10-K
March 29, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington D.C. 20549

FORM 10-K

(Mark One)
ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITY EXCHANGE ACT OF 1934
For the fiscal year ended December 29, 2018

or

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

Commission File Number 0-27598

IRIDEX CORPORATION

(Exact name of Registrant as specified in its charter)

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

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

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

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

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

Common Stock, par value $0.01 per share

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

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act"). Yes No

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (Section 229.405 of this chapter) is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

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

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

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

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

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

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

DOCUMENTS INCORPORATED BY REFERENCE

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

USE OF FORWARD-LOOKING STATEMENTS

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

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PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements are based on management's beliefs and assumptions and on information currently available to management. These statements include statements concerning future demand and order levels for the Company's products, future operating expenses, changes in personnel, product development and intellectual property related matters, the adoption and effect of Company products on its results, the markets in which the Company operates, usage and efficacy of the Company's products, the Company's future financial results, and the Company's strategic plans and objectives. In some cases, forward-looking statements can be identified by terminology, such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "intends," "potential," "continue," or the negative of such terms or other comparable terminology, although not all forward looking statements contain these words.

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

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

Item 1. Business

Overview

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

Our laser consoles consist of the following product lines:

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

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

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

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

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

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

Our Market Opportunity

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

Glaucoma

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

Pharmaceutical products represent a majority of this revenue estimate but have significant shortcomings. Pharmaceuticals are typically the first treatment method prescribed for glaucoma. These pharmaceutical treatments are commonly self-administered in drop form by the patients. Patients often have difficulties applying the pharmaceutical drops properly and may fail to appropriately or timely apply the medication, which may significantly reduce the effectiveness of the pharmaceutical. This poor adherence to and lack of persistence with glaucoma medication regimens have been documented in numerous independent studies, which often place the incidence of patient noncompliance up to or above 50%, particularly in patients on two or more prescription eye drops. Even when administered correctly, pharmaceuticals have demonstrated reduced efficacy over time.

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

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

Medical Retina

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

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

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

Our Solution

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

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

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

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

Our Strategy

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

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

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

Our Products

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

Laser Consoles

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

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

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

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

Delivery Devices

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

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

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

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

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

Single-use disposable probes

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

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

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

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

Research and Development

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

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

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

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

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

Customers and Customer Support

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

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

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

Sales and Marketing

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

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

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

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

Clinical Affairs

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

Operations

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

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

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

Competition

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

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

Patents and Proprietary Rights

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

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

Government Regulation

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