IRIDEX CORP
Form 10-K
April 02, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington D.C. 20549

FORM 10-K

þ Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
for the fiscal year ended January 3, 2015

or

¨ Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
for the transition period from to .

Commission file 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 Number)

1212 Terra Bella Avenue, Mountain View CA 94043-1824

(Address of principal executive offices)

(Zip Code)

(650) 940-4700

(Registrant’s telephone number, including area code)

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 þ

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 þ

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 þ No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes þ 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. þ

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

Large accelerated filer	¨	Accelerated filer	¨
Non-accelerated filer	¨	Smaller reporting company	þ

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

The aggregate market value of the voting common equity held by non-affiliates of the Registrant was approximately $49,005,071 as of June 27, 2014 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 12, 2015, Registrant had 9,858,612 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain parts of the Proxy Statement for the Registrant's 2015 Annual Meeting of Stockholders (the "Proxy Statement") are incorporated by reference into Part III of this Annual Report on Form 10-K.

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PART I

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, such as statements relating to levels of future sales and operating results; gross margins; sales levels generated by our independent sales force and through our distribution partners; future tax rates and availability of certain deferred potential tax benefits; leveraging our core business and increasing recurring revenues; broadening our product lines through product innovation and new treatments; general economic conditions; levels of international sales; market acceptance of our products; expectations for and sources of future revenues; our marketing programs and trends in healthcare; our ability to take advantage of economies-of-scale in product development and manufacturing; our current and future liquidity and capital requirements; efforts to decrease costs and manage cash flows; levels of future investment in research and development efforts; our ability to develop and introduce new products through strategic alliances, OEM relationships and acquisitions; the availability of components from third-party manufacturers; results of clinical studies and the status of our regulatory clearance; the impact of regulatory actions and determinations; and risks associated with bringing new products to market. In some cases, forward-looking statements can be identified by terminology, such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “intends,” “continue,” or the negative of such terms or other comparable terminology. 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 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, a Delaware corporation, and when the context so requires, our wholly owned non-operating subsidiaries, IRIS Medical Instruments, Inc. and Light Solutions Corporation, both California corporations, and IRIDEX France S.A.

Item 1. Business

General

IRIDEX Corporation is a leading worldwide provider of therapeutic based laser consoles, delivery devices and consumable instrumentation used to treat sight-threatening eye diseases in ophthalmology. In February 2012, we sold our aesthetics business to Cutera, Inc. The sale of the aesthetics business was a significant step forward in our strategy because it allowed us to focus solely on our ophthalmology business which is our core strength. Management believes that this path affords the Company with the best opportunity for long term profitable growth. In accordance with accounting principles generally accepted in the U.S. (“GAAP”), we have recast our financial information disclosed within this Form 10-K to show the results from our ophthalmology business as continuing operations and the results from our aesthetics business as discontinued operations for all periods presented. Our ophthalmology products are sold in the United States predominantly through a direct sales force and internationally through approximately 70 independent distributors in over 100 countries. Revenues from continuing operations in 2014, 2013 and 2012 were $42.8 million, $38.3 million and $33.9 million, respectively, and we generated net income (loss) from continuing operations of $10.0 million, $2.2 million and $(0.2) million, respectively. Total net income including income from discontinued operations for 2014, 2013 and 2012 was $10.0 million, $2.2 million and $1.4 million, respectively.

Our ophthalmology products consist of laser consoles, delivery devices and consumable instrumentation including laser probes, and are used in the treatment of serious eye diseases, including the three leading causes of irreversible blindness: diabetic retinopathy, glaucoma and age-related macular degeneration (“AMD”). In addition, our ophthalmology products are often used in vitrectomy procedures (used to treat proliferative diabetic retinopathy, macular holes, retinal tears and detachments) which are generally performed in the operating room and require a consumable single use intraocular laser probe (“EndoProbe”) to deliver light to the back of the eye together with other instrumentation. Our ophthalmology business includes (i) a recurring revenue component, consisting of sales of consumable products, predominantly single use laser probe devices and other instrumentation, combined with the repair, servicing and extended service contracts for our laser systems; and (ii) a capital component, consisting of the laser consoles combined with durable delivery devices (laser systems).

Our laser consoles consist of our IQ products which include IQ 532, IQ 577 and IQ 810 laser photocoagulation systems; and our OcuLight products including OcuLight TX, OcuLight SL, OcuLight SLx, OcuLight GL and OcuLight GLx laser photocoagulation systems. Certain of our laser consoles are capable of performing traditional continuous wavelength photocoagulation and our patented Fovea-Friendly MicroPulse laser photocoagulation. Towards the end of 2012, we introduced the TxCell Scanning Laser Delivery System, a delivery device which saves significant time in a variety of laser photocoagulation procedures by allowing physicians to deliver the laser in a multi-spot scanning mode, a more efficient method for these procedures than the traditional single spot mode. Our current family of laser probes includes a wide variety of products in 20, 23 and 25 gauge for vitreoretinal surgery and glaucoma surgery.

Ophthalmologists typically use our laser systems in hospital operating rooms ("OR") and ambulatory surgical centers, as well as their offices and clinics. In the OR and ambulatory surgical centers, ophthalmologists use our laser systems with either an indirect laser ophthalmoscope or a consumable, single use EndoProbe. Since our first shipment in 1990, more than 10,000 medical laser systems manufactured by IRIDEX have been sold worldwide.

IRIDEX Corporation was incorporated in California in February 1989 as IRIS Medical Instruments, Inc. In November 1995, 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. As used in this Annual Report on Form 10-K, the terms "Company," "IRIDEX," "we," "us" and "our" refer to IRIDEX Corporation, a Delaware corporation, and when the context so requires, our wholly owned subsidiaries, IRIS Medical Instruments, Inc. and Light Solutions Corporation, both California corporations, and IRIDEX France S.A.

Market

Ophthalmology is a large and growing global market. Growth is driven by the aging world population and the onset of diabetes, which is occurring at an epidemic rate, the introduction of new treatment approaches, and the realities of constrained health care system spending.

Diabetic retinopathy is a common complication of diabetes which impairs vision over time and if left untreated can lead to blindness. According to the International Diabetes Federation in an article published in November 2010 – at least 300 million people worldwide have diabetes, and this figure is likely to reach 438 million by the year 2030. According to the World Health Organization ("WHO") in their 2007 report – Vision 2020 The Right to Sight, after 20 years duration more than 75% of patients will have some form of diabetic retinopathy. Laser photocoagulation is currently the standard treatment for this disease, although there has been increased use of pharmaceuticals in recent years. A single treatment of continuous wavelength laser photocoagulation has been shown to stabilize the patient's vision over the long term. Continuous wavelength laser photocoagulation treatments typically take several months to be fully effective and have been demonstrated to last for many years. This treatment presents a very cost efficient model, and presents a risk of varying degrees of vision loss to the patient. Pharmaceuticals can stabilize vision in the near term, as treatments typically take a few days to be fully effective and have been demonstrated to last for weeks. However, patients receiving pharmaceutical treatment for diabetic retinopathy 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 injections is very costly to both the physician, in terms of time, and to the healthcare system, in terms of dollars spent on treatment. The short comings in treating this disease have led to a renewed interest in alternative approaches that may provide better patient outcomes.

Glaucoma is a leading cause of blindness in the world. WHO estimates that approximately 60.5 million people had glaucoma in 2010 and given the aging of the world's population, this number is anticipated to increase to nearly 80 million by 2020. Currently, glaucoma is not curable, and vision loss resulting from glaucoma currently cannot be regained. Glaucoma is often chronic and must be monitored for the duration of the patient's life. Most cases of glaucoma can be controlled and vision loss slowed or halted by treatment. 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. Even when administered correctly, pharmaceuticals have demonstrated reduced efficacy over time. When pharmaceuticals lose their effectiveness, laser treatment is often performed, and ultimately surgery may be required. The short comings in treating this disease have led to a renewed interest in surgical approaches that may allow treatment earlier and may result in better patient outcomes.

AMD is a disease that affects the aged. WHO indicates that, in 2006, 3 million people had lost their sight due to AMD and that the number affected is expected to double by the year 2020. Unfortunately, although pharmaceuticals are used to delay vision loss there is currently no cure for AMD. Pharmaceuticals require repeated injections in the eye every six to eight weeks, which are painful, increase the risk of adverse side effects, are costly, and their long term viability is unproven. Continuous wavelength laser photocoagulation can also be used to treat AMD, although it is used less frequently because the disease often requires the laser to be applied to the area of the retina responsible for central vision and the likelihood of significant loss of visual function is too high. The short comings in treating this disease has led to a renewed interest in investigating alternative approaches that might allow treatment earlier which would result in better patient outcomes.

Laser Photocoagulation

We produce laser photocoagulator systems, which are used in the treatment of many sight-threatening eye diseases, the majority of which are diseases of the retina and glaucoma. Photocoagulation delivers laser light to carefully targeted eye tissue and generates a local healing response. Laser photocoagulation has been demonstrated to be a safe and effective therapy with long-term benefits.

The traditional method of performing laser photocoagulation uses a mode which delivers continuously-on laser light, which is referred to as continuous wave ("CW") mode. Use of this mode typically leads to local tissue damage under the belief that tissue damage was necessary to generate the beneficial response associated with laser photocoagulation and can cause loss of visual function.

MicroPulse

MicroPulse is a method of delivering laser energy using a mode which chops the CW beam into short, microsecond long, laser pulses, which we have developed. There is a growing body of clinical evidence that demonstrates that MicroPulse therapy can generate the beneficial response associated with CW laser photocoagulation with no detectible tissue damage for the treatment of diabetic retinopathy, glaucoma and AMD. When used to treat diabetic retinopathy we refer to this as Fovea-Friendly because the laser can be used to treat the fovea without any loss of visual function typically associated with CW laser photocoagulation. Our IQ products are capable of MicroPulse as well as CW laser photocoagulation.

The IRIDEX 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 the sight-threatening eye diseases mentioned above. With the sale of our aesthetics business we are now focused exclusively on our ophthalmology business. At the end of 2014, we had $13.3 million in cash and no debt. Other than in 2012, when we incurred a net loss of $0.2 million from our ophthalmology operations, we generated net income from our ophthalmology operations in each of the past five years. It is our goal to continue to operate our business profitably.

Our strategy is to leverage our existing brand and distribution channel in the ophthalmology market promote the adoption of MicroPulse as a viable treatment alternative for diabetic retinopathy, glaucoma and AMD and consequently to introduce a broad array of products that:

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

To achieve these goals we are pursuing a number of organic initiatives which 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. See Item 1A. Risk Factors – Factors That May Affect Future Results – "Our future success depends on our ability to develop and successfully introduce new products and new applications." and "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."

Ophthalmic Products

We utilize a systems approach to product design. Each system includes a console, which generates the laser energy, and a number of interchangeable peripheral delivery devices for use in specific clinical applications. This approach allows our customers to purchase a basic console system and add additional delivery devices as their needs expand or as new applications develop. We believe that this systems approach is our distinguishing characteristic and also brings economies-of-scale to our product development and manufacturing efforts because individual applications do not require the design and manufacture of complete stand-alone products. Our primary capital equipment products range in price from $1,000 to $60,000 and consist of laser consoles and specialized durable delivery devices. Our line of consumable products range in price from $10 to $250 and consist primarily of cannulas and laser probes.

Consoles

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

Visible (Yellow) Photocoagulator Console. Our IQ 577 delivers visible (Yellow – 577nm) laser light. This product utilizes state of the art user interface technology and delivers a 577 wavelength which is at the peak of oxyhemoglobin absorption and allows ophthalmologists to obtain optimal results with lower power (more tissue sparing) compared with green wavelengths. The IQ 577 console weighs 18 pounds, has dimensions of 7.5”H x 12”W x 14”D, draws a maximum of 250 Watts of wall power, requires no water cooling, and has a remote control and wireless footswitch.

Visible (Green) Photocoagulator Console. Our IQ 532, OcuLight TX, GL and GLx Photocoagulators deliver visible (Green – 532nm) laser light. The IQ 532 product utilizes a user interface and product platform based on the IQ 577, as more fully described above. The OcuLight TX/GL/GLx have dimensions of 6”H x 12”W x 12”D, draw a maximum of 300 Watts of wall power and require no water cooling.

Infrared Photocoagulator Consoles. The OcuLight and IQ 810 photocoagulator consoles used by ophthalmologists are available in two infrared (810nm) output power ranges: the OcuLight SL at 2 Watts and the IQ 810 and OcuLight SLx at 3 Watts. The OcuLight consoles weigh 14 pounds and have dimensions of 4”H x 12”W x 12”D. The IQ 810 console weighs 11 pounds and has dimensions of 7”H x 12”W x 12”D. Neither requires external air nor water cooling.

MicroPulse Enabled Consoles. MicroPulse mode is offered as an option on our IQ 577, IQ 532 and some of our infrared laser photocoagulator systems.

Multi-wavelength Laser System Configurations. When used in conjunction with specific IRIDEX laser consoles, our Symphony slit lamp adapters can deliver multiple laser wavelengths from a single slit lamp installation. Our laser consoles, together with our Symphony slit lamp adapters, combine the clinical versatility and convenience of multiple wavelength delivery into one delivery device for retinal and glaucoma procedures. Currently, our compatible consoles are the OcuLight GLx and the OcuLight TX green laser consoles and the OcuLight SLx and the IQ 810 infrared laser consoles and the IQ 577 yellow laser console.

Ophthalmic Delivery Devices and Other Products

Our versatile family of consoles and delivery devices has been designed to accommodate the addition of new capabilities with a minimal incremental investment. Typically users of our consoles can add capabilities by simply purchasing new interchangeable delivery devices and utilizing them with their existing console. We have developed both consumable and durable delivery devices and expect to continue to develop additional delivery devices.

TxCell Scanning Laser Delivery System (“TxCell”). TxCell was introduced in the second half of 2012. It allows the physician to perform multi-spot pattern scanning for efficient retinal photocoagulation, confluent laser patterns for tissue-sparing MicroPulse protocols and allows for standard single spot photocoagulation. A second version was introduced at the end of 2013 that worked with a wider variety of slight lamps existing in the market and included a number of enhanced features.

TruFocus 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. The IRIDEX LIO is recognized as the “standard of the ophthalmic industry”.

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 photocoagulator delivery system. SLAs are used in treatment procedures for both retinal diseases and glaucoma. These devices are available in a wide variety of spot diameters. Our standard SLAs have a single fiber and deliver laser light from a single laser console. Our Symphony SLA has multiple fibers and can deliver laser light from two compatible laser consoles.

Operating Microscope Adapter (“OMA”). These adapters allow the physician to utilize a standard operating microscope in both diagnosis and laser treatment procedures. These devices are similar to SLAs, except that they are oriented horizontally and therefore can be used to deliver retinal photocoagulation to a supine patient.

EndoProbe. Our EndoProbe fiber optic delivery devices are used for endophotocoagulation, a retinal treatment procedure performed in the hospital operating room or surgery center during a vitrectomy procedure. These sterile

disposable probes are available in tapered, angled, stepped, aspirating, illuminating, and adjustable styles. The EndoProbe is offered in a wide variety of gauges.

G-Probe. The G-Probe is used in procedures to treat medically and surgically uncontrolled glaucoma, in many instances replacing cyclocryotherapy, or freezing of eye tissues. The G-Probe's non-invasive procedure takes approximately ten minutes, is performed on an anesthetized eye in the doctor's office, and results in less pain and fewer adverse side effects than cyclocryotherapy. The G-Probe is a sterile single-use product.

DioPexy Probe. The DioPexy Probe is a hand-held instrument which is used in procedures to treat retinal tears, and breaks non-invasively through the sclera, as an alternative method of attaching the retina. Our DioPexy Probe results in increased precision, less pain and less inflammation than traditional cryotherapy.

GreenTip™ Soft Tip Cannula. The GreenTip cannula allows surgeons to effectively visualize and access the proximity of the retina while performing a fluid air exchange during a vitrectomy procedure. Benefits include optimal contrast against the retina, maximized visualization and greater protection of the retina with its unique atraumatic silicone tip. The GreenTip cannula is a sterile disposable single-use product.

MoistAir™ In-Line Air Humidifier. The MoistAir Humidifying Chamber connects to the air line and provides humidified air to the eye during fluid air exchange. Studies have shown that the use of humidified air can substantially reduce the dehydrating effects, delay lens feathering, protect corneal endothelium, and may prevent visual field loss defects after macular hole surgery. The MoistAir Humidifying Chamber is a sterile disposable single use product.

Ophthalmology Treatments

The following chart lists the procedures for treating ophthalmic diseases that can be addressed by utilizing our ophthalmic laser systems. These procedures typically are performed in an OR, ambulatory surgical centers or clinic/outpatient settings and are non-elective and covered by insurance.

	Procedure	Console	Delivery Devices and Other Product	Mode
Age-related Macular Degeneration	Retinal Photocoagulation	Infrared & Visible	Slit Lamp Adapter	CW
Diabetic Retinopathy				
Macular Edema	Grid Retinal Photocoagulation	Infrared & Visible	Slit Lamp Adapter & Operating Microscope Adapter,	CW or MicroPulse
	Focal Retinal Photocoagulation	Visible	Slit Lamp Adapter	
Proliferative	Pan-Retinal Photocoagulation Vitrectomy Procedure	Infrared & Visible	Slit Lamp Adapter, Operating Microscope Adapter, Laser Indirect Ophthalmoscope, EndoProbe*GreenTip cannula*	CW or MicroPulse
Glaucoma				
Primary Open-Angle	Trabeculoplasty	Infrared & Visible	Slit Lamp Adapter	CW or MicroPulse
Angle-closure	Iridotomy		Slit Lamp Adapter	CW

		Infrared & Visible		
Uncontrolled Glaucoma	Transscleral Cyclophotocoagulation	Infrared	G-Probe*	CW
Retinal Tears and Detachments	Retinopexy Retinal Photocoagulation Vitrectomy Procedure	Infrared & Visible	Slit Lamp Adapter, Laser Indirect Ophthalmoscope, Operating Microscope Adapter, EndoProbe* GreenTip cannula*, MoistAir Humidifying Chamber*	CW
	Transscleral Retinal Photocoagulation	Infrared	DioPexy Probe	CW
Retinopathy of Prematurity	Retinal Photocoagulation	Infrared	Laser Indirect Ophthalmoscope	CW
Ocular Tumors	Retinal Photocoagulation	Infrared	Slit Lamp Adapter, Operating Microscope Adapter, Laser Indirect Ophthalmoscope	CW
Macular Holes	Vitrectomy Procedure	Visible	EndoProbe*	CW

*Consumable and disposable products

Research and Development

We have close working relationships with researchers, clinicians and practicing physicians around the world who provide new ideas, test the feasibility of these new ideas 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 13 engineers, scientists and regulatory professionals with experience in various aspects of medical products, laser systems, delivery devices and clinical techniques 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, firmware and delivery devices. The R&D process integrates all of the 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 and/or partnering with physicians to gain specialized expertise and understanding. Research efforts are directed toward the development of new products and new applications for our existing 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 researching and improving the treatment of serious eye diseases such as diabetic retinopathy and glaucoma, and AMD. The objectives of developing new treatments and applications are to expand the potential patient population, to more effectively and more economically treat diseases, to treat patients earlier in the treatment regimen and to reduce the side effects of treatment.

We spent $4.6 million on R&D in our continuing operations in 2014, $3.7 million in 2013 and $4.4 million in 2012.

We consider clinical projects to be a component of our R&D efforts and they may or may not result in additional commercial opportunities. See Item 1A. Risk Factors - Factors That May Affect Future Results – "While we devote significant resources to research and development, our research and development may not lead to new products that achieve commercial success" and "The clinical trial process required to obtain regulatory approvals is costly and uncertain, and could result in delays in new product introductions or even an inability to release a product."

Customers and Customer Support

Our products are currently sold for use by ophthalmologists specializing in the treatment of eye disease in the retina, glaucoma and pediatrics 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 2014, 2013 and 2012.

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 ophthalmology 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 predominantly through our direct sales force and internationally through approximately 70 independent distributors into over 100 countries. Currently we have a direct sales force of 12 employees who are engaged in sales efforts within the United States and 5 employees engaged in managing our distribution sales efforts internationally. We also contract for the services of 15 independent sales representatives to supplement our U.S. direct sales efforts. Our sales are administered through our corporate headquarters in Mountain View, California. See Item 1A. Risk Factors—Factors That May Affect Future Results – "We rely on our direct and independent sales force and network of international distributors to sell our products and any failure to maintain our direct sales force and distributor relationships could harm our business."

International sales represented 47.2%, 45.0% and 45.4% of our sales in 2014, 2013 and 2012, 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. See Item 1A. Risk Factors - Factors That May Affect Future Results - “We depend on international sales for a significant portion of our operating results.”

In the past, we maintained two wholly owned subsidiaries, one located in the United Kingdom (“UK”) and the other in France; both of which were exclusively engaged in supporting our aesthetics business. In June 2008, we transitioned the responsibility for the sales and service of our aesthetics products in the UK to an independent distributor and during 2011 we deregistered the legal entity. Upon closing the sale of the aesthetics business to Cutera, Inc. in February 2012, our French subsidiary ceased operations. We do not currently maintain any operating subsidiaries.

To support our sales process, we conduct marketing programs which include: our website, clinical education, email marketing, trade shows, public relations, market research, 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.

In March 2013, we entered into a global distribution and supply agreement with Peregrine Surgical Ltd. (“Peregrine”). Under the agreement, we became a worldwide distributor for Peregrine labeled products and Peregrine became part of the IRIDEX supply chain.

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 33 employees engaged in manufacturing activities for these products.

The medical devices manufactured by us are subject to extensive regulation by numerous governmental authorities, including federal, state, and foreign governmental agencies. The principal regulator in the United States is the Food and Drug Administration (“FDA”). 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 Directive. 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 August 2008, we received FDA 510(k) clearance on our family of IRIDEX IQ laser systems. This clearance covers the IRIDEX IQ 532, IQ 577, IQ 630-670, and IQ 810 laser systems and their associated delivery devices to deliver laser energy in either CW-Pulse, MicroPulse or LongPulse mode. These laser systems are intended for a wide range of specific applications in the medical specialties of ophthalmology. See Item 1A. Risk Factors - Factors That May Affect Future Results - “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.", "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." and "If we modify one of our FDA approved devices, we may need to seek reapproval, which, if not granted, would prevent us from selling our modified products or cause us to redesign our products."

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. See Item 1A. Risk Factors - Factors That May Affect Future Results - "We depend on sole source or limited source suppliers."

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 Directive 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 Directive. This allows us to CE mark any product upon our internal verification of compliance to all applicable European standards. 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.

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 competitors in ophthalmology are Alcon Inc., Carl Zeiss Meditec AG, Nidek Co. Ltd, Synergetics, Topcon Corporation, Ellex Medical Lasers, Ltd., Quantel Medical SA, and Lumenis Ltd. Most of these companies currently offer a competitive, semiconductor-based laser system for ophthalmology. Also within ophthalmology, pharmaceutical alternative treatments for AMD and diabetic macular edema (“DME”) such as Lucentis/Avastin (Genentech), Eylea (Regeneron), Macugen (OSI Pharmaceuticals) and Ozurdex (Allergan), and to a lesser extent Visudyne (Novartis), compete rigorously with traditional laser procedures.

Some ophthalmic 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. See Item 1A. Risk Factors - Factors That May Affect Future Results - “We face strong competition in our markets and expect the level of competition to grow in the foreseeable future.”

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. We have been issued 26 United States patents and 17 foreign patents on the technologies related to our continuing products and processes, which have expiration dates ranging from 2015 to 2028. We have 13 pending patent applications in the United States and 19 foreign pending patent applications that have been filed. 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. See Item 1A.Risk Factors - Factors That May Affect Future Results - “We rely on patents and proprietary rights to protect our intellectual property and business.”

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, as amended, and the regulations promulgated thereunder ("FDA Act"), 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 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, such as our IQ 810 system, 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, but we believe that new 510(k) clearances are not required for these modifications. 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 FDA 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 Health Services ("CDHS"), 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 is covered by the Export Amendment of 1996, which greatly expanded the export of approved and unapproved United States medical devices. However, some foreign countries require manufacturers to provide an FDA certificate of products for export ("CPE") 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 a CPE if significant outstanding QSR violations exist.

We are also regulated under the Radiation Control for Health and Safety 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.

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. See Item 1A Risk Factors - Factors That May Affect Future Results - "Our operating results may be adversely affected by uncertainty regarding healthcare reform measures and changes in third-party coverage and reimbursement policies".

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

Currently, we have a total of 106 full-time equivalent employees engaged in our ongoing ophthalmology operations, including 52 in operations (including manufacturing, quality, logistics and service), 28 in sales and marketing which does not include the 15 independent sales representatives, 13 in research and development and 13 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. At January 3, 2015, we employed 22 such persons. 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 SEC’s 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 Securities and Exchange Commission.

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.

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 January 3, 2015, our international ophthalmology sales were $20.2 million or 47.2% of total revenues. We anticipate that international sales will continue to account for a significant portion of our revenues in the foreseeable future. For our continuing ophthalmology business, none of our international revenues and costs has been denominated in foreign currencies. As a result, an increase in the value of the U.S. dollar relative to foreign currencies makes our products more expensive and thus less competitive in foreign markets. Our international operations and sales are subject to a number of risks and potential costs, including:

- fluctuations in foreign currency exchange rates;
- 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;
- 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; and
- multiple protectionist, adverse and changing foreign governmental laws and regulations.

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. 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 and profitability.

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;
- 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;
- general economic uncertainties and political concerns;
- 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; 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 quarter. 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.

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. For fiscal year 2014, the trading price of our common stock fluctuated from a low of $6.41 per share to a high of $11.00 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.

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;
- 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 EndoProbe devices and service. 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 our products, 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 devices used for ophthalmic treatment procedures is intense and is expected to increase. Our competitive position depends on a number of factors including product performance, characteristics and functionality, ease of use, scalability, durability and cost. Our principal competitors in ophthalmology are Alcon Inc., Carl Zeiss Meditec AG, Nidek Co. Ltd., Synergetics, Topcon Corporation, Ellex Medical Lasers, Ltd., Quantel Medical SA, and Lumenis Ltd. Most of these companies currently offer a competitive, semiconductor-based laser system for ophthalmology. Also within ophthalmology, pharmaceutical alternative treatments for AMD and DME such as Lucentis/Avastin (Genentech), Eylea (Regeneron), Macugen (OSI Pharmaceuticals) and Ozurdex (Allergan), and to a lesser extent Visudyne (Novartis), compete rigorously with traditional laser procedures. A number of these competitors have substantially greater financial, engineering, product development, manufacturing, marketing and technical resources than we do, including greater name recognition, and benefit from long-standing customer relationships. Some medical companies, academic and research institutions, or others, may develop new technologies or therapies that are more effective in treating conditions targeted by us or are less expensive than our current or future products. 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.

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. 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, 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 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.

Our ophthalmology 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. 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.

Our future success depends on our ability to develop and successfully introduce new products and new applications.

Our future success is dependent upon, among other factors, our ability to develop, obtain regulatory approval or clearance of, manufacture and market new products. 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 may also be 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 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 Soft Tip 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 arrangements of any current or future clinical or commercial 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.

While we devote significant resources to research and development, our research and development may not lead to new products that achieve commercial success.

The Company's ability to generate incremental revenue growth will depend, in part, on the successful outcome of research and development activities, including 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. The products currently in our development pipeline may not be approved by regulatory entities and may not be commercially successful, and our current and planned products could be surpassed by more effective or advanced products of current or future competitors. Therefore, even if we are able to successfully develop enhancements or new generations of our products, these enhancements or new generations of products may not produce revenue in excess of the costs of development and they may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features.

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.

Since 1989, we have completed 6 acquisitions. 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;
- 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.

Any one or more of these factors stated above could have a material adverse effect on our business, financial condition or results of operations. Furthermore, acquisitions could materially impair our operating results by causing us to amortize acquired assets, incur acquisition expenses and add debt.

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 and relationships with independent distributors outside the United States. Currently our direct and independent sales forces within the United States consists of approximately 13 employees and 15 independent representatives, respectively. We maintain relationships with approximately 70 independent distributors internationally selling our products into over 100 countries, managed by a team of 5 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 entirely 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.

If we cannot increase our sales volumes, reduce our costs or introduce higher margin products to offset anticipated 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.

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. We have been issued 26 United States patents and 17 foreign patents on the technologies related to our products and processes. We have 13 pending patent applications in the United States and 19 foreign pending patent applications that have been filed. 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 after November 2000 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 with regards to international patent applications, we cannot assure you 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 assure you 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.

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 the necessary components and materials. Lead times for components vary significantly and depend on numerous factors, including the specific supplier, the size of the order, contract terms and current market demand for such components. 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 component and materials 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 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 in the quantities that we require;
- delays in delivery or failure of suppliers to deliver critical components on the dates we require;
- failure of suppliers to manufacture components to our specifications, and potentially reduced quality; and
- inability to obtain components 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. 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 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 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 in the quantity and quality desired and at the prices we have budgeted.

If we fail to maintain our relationships with health care providers, customers may not buy our products and our revenue and profitability may decline.

We market our products to numerous health care providers, including physicians, hospitals, ambulatory surgical centers, 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.

We face manufacturing risks.

The manufacture of our infrared and visible laser consoles and the related delivery devices is a highly complex and precise process. We assemble critical subassemblies and substantially all of our final products at our facility in Mountain View, California. We may experience manufacturing difficulties, quality control issues or assembly constraints, particularly with regard to new products that we may introduce. 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 and as a result, product shipments to our customers could be delayed, which would negatively impact our net revenues.

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.

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 FDA 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 undergo rigorous testing and an extensive regulatory review process implemented by the FDA under federal law. Unless otherwise exempt, a device manufacturer must obtain market clearance through either the 510(k) premarket notification process or the lengthier premarket approval application 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 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 additional regulations on manufacturers of approved medical devices. We are required to comply with the applicable Quality System regulations and our manufacturing facilities are subject to ongoing periodic inspections by the FDA and corresponding state agencies, including unannounced inspections, and must be licensed as part of the product approval process before being utilized for commercial manufacturing. Noncompliance with the applicable requirements can result in, among other things, 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.

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 Directive 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.

The clinical trial process required to obtain regulatory approvals is costly and uncertain, and could result in delays in new product introductions or even an inability to release a product.

The clinical trials required to obtain regulatory approvals for our products are complex and expensive and their outcomes are uncertain. When we do embark upon clinical trials, we incur substantial expense for, and devote significant time to, these trials but cannot be certain that the trials will ever result in the commercial sale of a product. We may suffer significant setbacks in clinical trials, even after earlier clinical trials showed promising results. Any of our products may 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 may suspend or terminate clinical trials at any time if they or we believe the trial participants face 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 Quality System Regulation. 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, such as those described in the risk factor above, which would cause our sales and business to suffer.

If we modify one of our FDA approved devices, we may need to seek reapproval, which, if not granted, 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 premarket approval. 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 out 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 CW systems or alternative treatment methods may increase the risk that our products will be misused. 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 more expensive to our customers, which may decrease demand for our products. Any reduction in the sales of our products would cause our business to suffer.