IRIDEX CORP
Form 10-K
March 27, 2014

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 December 28, 2013

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 $54,494,721 as of June 28, 2013 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 11, 2014, Registrant had 9,993,948 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain parts of the Proxy Statement for the Registrant's 2014 Annual Meeting of Stockholders (the "Proxy Statement") are incorporated by reference into Part III of this Annual Report on Form 10-K.

Table of Contents

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 though 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 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 2013, 2012 and 2011 were $38.3 million, $33.9 million and $33.2 million, respectively, and we generated net income (loss) from continuing operations of $2.2 million, $(0.2) million and $2.1 million, respectively. Total net income including income from discontinued operations for 2013, 2012 and 2011 was $2.2 million, $1.4 million and $2.6 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 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. Often, glaucoma is 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. Laser photocoagulation is the standard-of-care for 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 2013, the Company had $13.4 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 delivers visible (Green – 532nm) laser light. This product utilizes a user interface and product platform based on the IQ 577, as more fully described above, as well as our OcuLight TX, OcuLight GL and OcuLight GLx Photocoagulators. 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 some of our infrared and visible 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 consumable multi-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	Infrared & Visible	Slit Lamp Adapter	CW
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 11 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 $3.7 million on R&D in our continuing operations in 2013, $4.4 million in 2012 and $3.9 million in 2011.

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 2013, 2012 and 2011.

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 11 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 13 independent sales representatives. 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 45.0%, 45.4% and 44.4% of our sales in 2013, 2012 and 2011, 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 the imposition of governmental controls, currency fluctuations, 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 the 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 Cutrera, 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, which 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, the Company entered into a global distribution and supply agreement with Peregrine Surgical Ltd. (“Peregrine”). Under the agreement, IRIDEX will become a worldwide distributor for Peregrine labeled products and Peregrine will become 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 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 2014 to 2028. We have 12 pending patent applications in the United States and 11 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, or 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 101 full-time equivalent employees engaged in our ongoing ophthalmology operations, including 48 in operations (including manufacturing, quality, logistics and service), 28 in sales and marketing which does not include the 13 independent sales representatives, 11 in research and development and 14 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 December 28, 2013, we employed 17 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.

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:

- 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;
- 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;
- our long and highly variable sales cycle;
- changes in the prices at which we can sell our products, including the impact of changes in exchange rates;
- 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 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 2013, the closing price of our common stock fluctuated from a low of $3.76 per share to a high of $10.46 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.

14

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. However, denial of coverage and reimbursement of our products would 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.

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

We derive, and expect to continue to derive, a large portion of our revenues from international sales. For the fiscal year ended December 28, 2013, our international ophthalmology sales were $17.2 million or 45.0% of total revenue. 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:

- impact of recessions in global economies and availability of credit;
- impact of international conflicts, terrorist and military activity, civil unrest;
- fluctuations in foreign currency exchange rates;
- foreign certification requirements, including continued ability to use the “CE” mark in Europe, and other local regulatory requirements;

- performance of our international channel of distributors;
- longer accounts receivable collection periods;
- differing local product preferences and product requirements;
- cultural differences;
- changes in foreign medical reimbursement and coverage policies and programs;
- political and economic instability;
- 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.

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. Historically, we have collaborated with Bausch & Lomb to design and manufacture a solid-state green wavelength (532nm) laser photocoagulator module for Bausch & Lomb, called the Millennium Endolase module. Bausch & Lomb has introduced a new product to replace the product that included the Millennium Endolase module and as such we have seen sales to Bausch & Lomb decline and we anticipate that sales will continue to decline. 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 12 employees and 10 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.

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.

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 12 pending patent applications in the United States and 11 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 obtaining 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.

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

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

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

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

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

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

The FDA and similar governmental authorities in other countries in which we market and sell our products have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. A government mandated recall, or a voluntary recall by us, could occur as a result of component failures, manufacturing errors or design defects, including defects in labeling. A recall could divert management's attention, cause us to incur significant expenses, harm our reputation with customers and negatively affect our future sales.

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

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

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

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

to price fluctuations and shortages which can affect our ability to obtain the manufactured materials we rely on at favorable terms or from consistent sources. These changes could have an adverse impact on our ability to manufacture and market our devices and products.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We lease 37,000 square feet of space in Mountain View, California and our lease expires in February 2015. This facility is being substantially utilized for all of our manufacturing, research and development efforts and also serves as our corporate headquarters.

Management believes that these facilities are adequate for our current needs and that suitable additional space or an alternative space would be available as needed in the future on commercially reasonable terms.

Item 3. Legal Proceedings

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

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information for Common Equity

Our common stock is currently and since our initial public offering on February 15, 1996, has been quoted on the NASDAQ Global Market under the symbol "IRIX". The following table sets forth for the periods indicated the high and low sales prices for our common stock, as reported on the NASDAQ Global Market.

	High	Low
Fiscal 2013		
Fourth Quarter	$10.74	$5.80
Third Quarter	$6.58	$5.30
Second Quarter	$6.57	$4.01
First Quarter	$5.00	$3.76
Fiscal 2012		
Fourth Quarter	$4.09	$3.54
Third Quarter	$4.09	$3.07
Second Quarter	$4.49	$3.12
First Quarter	$4.50	$3.61

On March 11, 2014 the closing price on the NASDAQ Global Market for our common stock was $9.43 per share. As of March 11, 2014, there were approximately 53 holders of record (not in street name) of our common stock. Because many of our shares of common stock are held by brokers and other institutions on behalf of our stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Dividend Policy

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

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

The following table provides information with respect to acquisitions by the Company of shares of its common stock during the quarter ended December 28, 2013.

ISSUER PURCHASES OF EQUITY SECURITIES

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of a Publicly Announced Plan	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plan

	(1)	(2)		
09/29/13 to 11/02/13	38,488	$ 6.03	38,488	2,574,065
11/03/13 to 11/30/13	—	$ —	—	2,574,065
12/01/13 to 12/28/13	—	$ —	—	2,574,065
Total	38,488	$ 6.03	38,488	2,574,065

(1) On February 28, 2013, the Board of Directors announced a $3.0 million stock repurchase program expiring in February 2014. The above table reflects the repurchase of shares of our common stock in the open market or privately negotiated transactions in accordance with the stock repurchase program during the fourth quarter 2013. As of December 28, 2013, the Company has repurchased 75,025 shares for $425,935 under this program. Each repurchase was financed by available cash balances and cash from operations. On February 27, 2014, the Board of Directors approved the extension of the plan for an additional year and approximately $2.6 million remains available for stock repurchases. All Company stock repurchases during fiscal 2013 were made in accordance with this repurchase program.

(2) Average price paid per share of common stock repurchased represents the execution price, including commissions paid to brokers.

Item 6. Selected Financial Data

Not applicable.

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

Overview

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. We view this as a significant step forward in our strategy because it allows 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 US GAAP we have disclosed the financial results from our aesthetics business as discontinued operations. This discussion and analysis will focus primarily on our ophthalmology business because this is our continuing business and therefore provides more relevant and comparable information to the reader of our financial statements both on a retrospective and prospective basis. Our ophthalmology products are sold in the United States predominantly through a direct sales force and internationally through approximately 70 independent distributors into over 100 countries.

We manage and evaluate our business in one segment - ophthalmology. We break down this segment by geography—Domestic (U.S.) and International (the rest of the world). In addition, we review trends by laser system sales (consoles and durable delivery devices) and recurring sales (single use consumable laser probes and other associated instrumentation ("consumables"), service and support).

Our ophthalmology revenues arise primarily from the sale of our IQ and OcuLight laser systems, consumables, service and support activities. Our current family of IQ products includes IQ 532, IQ 577 and IQ 810 laser photocoagulation systems and our OcuLight products include OcuLight TX, OcuLight Symphony ("Laser Delivery System"), OcuLight SL, OcuLight SLx, OcuLight GL and OcuLight GLx laser photocoagulation systems. Certain of our laser systems 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 which saves significant time in a variety of laser photocoagulation procedures in 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.

Sales to international distributors are made on open credit terms or letters of credit and are currently denominated in U.S. dollars and accordingly, are not subject to risks associated with currency fluctuations.

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

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

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

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

Results of Operations - 2013, 2012 and 2011

Our fiscal year ends on the Saturday closest to December 31. Fiscal 2013 ended on December 28, 2013, fiscal 2012 ended on December 29, 2012, and fiscal 2011 ended on December 31, 2011. Fiscal years 2013, 2012 and 2011 each included 52 weeks of operations.

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

	Percentage of Revenue Years Ended		
	FY 2013 Dec 28, 2013	FY 2012 Dec 29, 2012	FY 2011 Dec 31, 2011
Revenues:			
Total revenues	100.0%	100.0 %	100.0 %
Cost of revenues	51.4	51.7	50.9
Gross margin	48.6	48.3	49.1
Operating expenses:			
Research and development	9.6	13.0	11.8
Sales and marketing	20.2	23.3	22.4
General and administrative	13.1	14.5	12.8
Proceeds from demutualization of insurance carrier	(1.2)	—	—
Legal settlement, net of expenses	—	—	(3.8)
Total operating expense	41.7	50.8	43.2
Income (loss) from continuing operations	6.9	(2.5)	5.9
Legal settlement	—	2.3	2.4
Interest and other expense, net	(1.0)	(0.6)	(0.9)
Income (loss) from continuing operations before income taxes	5.9	(0.8)	7.4
Provision for (benefit from) income taxes	0.1	(0.3)	0.9
Income (loss) from continuing operations, net of tax	5.8	(0.5)	6.5
Income (loss) from discontinued operations, net of tax	—	(0.8)	1.4
Gain on sale of discontinued operations, net of tax	—	5.5	—
Income from discontinued operations, net of tax	—	4.7	1.4
Net income	5.8 %	4.2 %	7.9 %

Comparison of 2013 and 2012

Revenues.

Our total revenues increased $4.4 million or 13.0% from $33.9 million in 2012 to $38.3 million in 2013, as a result of increases in both system sales and in our recurring revenues. The increase in system sales was due to an increase in sales of our IQ lasers that features MicroPulse, both domestic and international. The increase in recurring revenues was attributable to the inclusion of sales generated by the independent sales force resulting from the Peregrine distribution and supply agreement, as well as an increase in sales of our licensed GreenTip product by our distribution partner, Alcon, Inc. (“Alcon”). OEM sales are expected to cease shortly as our OEM partner, Bausch & Lomb, Incorporated (“B&L”), has discontinued selling this product.

(in millions)	FY 2013	FY 2012	Change in $	Change in %
Systems - domestic	$ 8.4	$ 7.1	$ 1.3	18.3 %
Systems - international	10.9	9.4	1.5	16.0 %
Recurring revenues	18.7	17.1	1.6	9.4 %

OEM	0.3	0.3	—	—	
Total revenues	$ 38.3	$ 33.9	$ 4.4	13.0	%

Gross Profit.

Gross profit was $18.6 million in 2013 compared with $16.3 million in 2012, an increase of $2.2 million or 13.7%. The increase in gross profit was primarily due to the increase in revenues. Gross margin as a percent of revenue was 48.6% compared with 48.3%, an increase of 0.3% due to overhead efficiencies and cost reductions, which were partly offset by a change in product mix.

Gross margins as a percentage of revenues are expected to continue to fluctuate due to changes in the relative proportions of domestic and international sales, the product mix of sales, manufacturing variances, total unit volume changes that lead to greater or lesser production efficiencies and a variety of other factors. See Item 1A. “Risk Factors - Factors That May Affect Future Results - ‘Our operating results may fluctuate from quarter to quarter and year to year.”

Research and Development.

R&D expenses decreased $0.7 million or 16.0% from $4.4 million in 2012 to $3.7 million in 2013. The decrease in spending was primarily attributable to a decrease in headcount and associated costs. Additionally, project development materials decreased as a result of units being released to production. We anticipate an increase in the spending level in R&D in support of new products and certain product cost reduction programs we are initiating going forward.

Sales and Marketing.

Sales and marketing expenses decreased $0.2 million or 2.2%, from $7.9 million in 2012 to $7.7 in 2013. Marketing expenditures decreased $0.6 million due to reduced headcount and program spending as we transitioned from traditional marketing programs to online digital marketing programs, these savings were, partly offset by costs associated with the expansion of our independent sales force resulting from the Peregrine agreement and increased commissions associated with increased revenues.

General and Administrative.

General and administrative expenses increased $0.1 million or 2.0%, from $4.9 million in 2012 to $5.0 million in 2013. The 2012 expenses included $0.7 million in severance and related costs. Excluding these costs, the increase of $0.8 million was primarily attributable to the introduction of the Medical Device Tax introduced in connection with the Patient Protection and Affordable Care Act in 2013, which cost us $0.3 million for the year and an increase in compensation charges of $0.4 million for the year.

Proceeds from Demutualization of Insurance Carrier.

In January 2013, we received $0.5 million as a result of the demutualization of our product and liability insurance carrier.

Other Income (expense).

The legal settlement relates to payments received from Synergetics, Inc. associated with a 2007 settlement of legal claims for patent infringement. The $0.8 million received in 2012 represented the final payment.

Interest and other expense, net consisted primarily of expense recorded for the fair value re-measurement of the contingent earn-out liabilities incurred as a result of the Company’s recent acquisitions and was $0.4 million in 2013 and $0.2 million in 2012.

Income Taxes.

We recorded a provision for income taxes of $31 thousand for the year ended December 28, 2013 compared to a benefit for income taxes of $0.1 million for the year ended December 29, 2012. Our effective tax rate on continued operations for the year ended December 28, 2013 was 1.4% compared to an effective tax rate of 37% for the year ended December 29, 2012. Our effective tax rate decreased due mainly to the change from 2012 pretax loss from continuing operations of $0.3 million to 2013 pretax income from continuing operations of $2.3 million. Our tax rate is benefiting from a decrease in the valuation allowance we currently have booked against our deferred tax asset and benefiting from a deduction under Section 199 of the Internal Revenue Code of 1986, as amended (“IRC”). Ultimately, assuming we remain profitable, the entire valuation allowance will be released and our tax rate will return to more normal levels. At the end of 2013, the valuation allowance totaled $10.0 million.

Comparison of 2012 and 2011

Revenues.

Total revenues from continuing operations in 2012 were $33.9 million compared with $33.2 million in 2011, an increase of $0.7 million or 2.1%. The increase was due primarily to our recurring revenues which improved as a result of the onset of revenues from the licensing and distribution agreement with Alcon. Our ophthalmology system revenues remained consistent period to period. Our OEM revenue continued to decline as anticipated because this revenue is generated from a product that is now in its end of life phase.

(in millions)	FY 2012	FY 2011	Change in $	Change in %
Systems - domestic	$ 7.1	$ 7.2	$ (0.1)	(1.4)%
Systems - international	9.4	9.3	0.1	1.1 %
Recurring revenues	17.1	16.2	0.9	5.6 %
OEM	0.3	0.5	(0.2)	(40.0)%
Total revenues	$ 33.9	$ 33.2	$ 0.7	2.1 %

Gross Profit.

Gross profit remained level at $16.3 million in 2012 even though revenues increased as a result of a decrease in gross margin to 48.3% in 2012, from 49.1% in 2011. The reduction in gross margin was primarily attributable to increased manufacturing and service costs.

Research and Development.

Research and development expenses increased $0.5 million or 12.1%, from $3.9 million in 2011 to $4.4 million in 2012. The increase is attributable to increases in headcount and project material costs incurred in engineering development projects, and patent expenses as the Company continued to focus on new product introductions.

Sales and Marketing.

Sales and marketing expenses increased $0.4 million or 5.9%, from $7.5 million in 2011 to $7.9 million in 2012. The increase is primarily attributable to increased personnel costs associated with increased headcount and marketing programs.

General and Administrative.

General and administrative expenses increased $0.7 million or 15.7%, from $4.3 million in 2011 to $4.9 million in 2012. The increase in expenses was primarily attributable to employee severance and related costs taken as part of streamlining the Company’s operations in the latter half of the year.

Legal Settlement and Other Expense, Net.

The Company received the final annual installment of $0.8 million from the settlement with Synergetics of legal claims related to patent infringement which was consistent with the amount received in 2011. During 2012, the remeasurement on the fair value of the earn-out liability from prior acquisitions resulted in an expense of $0.2 million.

Income Taxes.

We recorded a benefit for income taxes on continuing operations of $0.1 million and an effective tax rate of 37% for fiscal year 2012 compared to a provision for income taxes of $0.3 million and an effective tax rate of 12% for fiscal year 2011. Our tax rate is benefiting from a reduction in the valuation allowance we currently have booked against our deferred tax asset.

Liquidity and Capital Resources

Comparison of 2013 and 2012

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

As of December 28, 2013, we had cash and cash equivalents of $13.4 million, no debt and working capital of $24.6 million compared to cash and cash equivalents of $11.9 million, no debt and working capital of $20.7 million as of December 29, 2012.

The increase in cash and cash equivalents for the year ended December 28, 2013 was generated primarily by income from continuing operations of $2.2 million, the add back of non-cash items of $1.6 million, partially offset by changes in working capital by $3.1 million. We used $0.4 million on capital expenditures and $0.4 million on paying the contingent earn-out liability arising from our acquisitions of RetinaLabs and Ocunetics. Exercises of stock options generated $1.5 million and we spent $0.4 million to purchase stock under our stock repurchase program, and we received $0.5 million in cash from the release of funds held in escrow related to our 2012 sale of the aesthetics business. See Item 2, Unregistered Sales of Equity Securities and Use of Proceeds in Part II, Other Information, for additional information.

Management is of the opinion that the Company’s current cash and cash equivalents together with our ability to generate cash flows from operations provide sufficient liquidity to operate for the next 12 months.

Comparison of 2012 and 2011

During 2012, net cash used in continuing operating activities was $1.1 million. The use of cash resulted primarily from a net loss from continuing operations of $0.2 million plus changes in working capital consuming an additional $2.0 million partially offset by certain non-cash items of $1.1 million. This compares to net cash provided by continuing operating activities in 2011 of $2.3 million which was generated from net income from continuing operations of $2.1 million the add back of non-cash items of $1.2 million less changes in working capital of $1.0 million.

As of December 29, 2012, we had cash and cash equivalents of $11.9 million, no debt outstanding and working capital of $20.7 million compared to cash and cash equivalents of $10.8 million, no debt and working capital of $20.6 million as of December 31, 2011.

Contractual Payment Obligations

As of December 28, 2013, our contractual payment obligations that were fixed and determinable to third parties for non-cancelable operating leases, contract manufacturers and other purchase commitments were as follows (in thousands):

	Payments Due by Period			
	Total	<1 year	1-3 years	3-5 years
Operating leases payments	$1,198	$866	$ 318	$ 14
Commitments to contract manufacturers and suppliers	3,053	1,178	1,500	375
Total contractual cash obligations	$4,251	$2,044	$ 1,818	$ 389

Critical Accounting Policies

Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, net sales and expenses, and the related disclosures. We base our estimates on historical experience, our knowledge of economic and market factors and various other assumptions we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. We believe the following critical accounting policies are affected by significant estimates, assumptions, and judgments used in the preparation of our consolidated financial statements.

Discontinued Operations.

Discontinued operations are accounted for and presented in accordance with Accounting Standards Codification (“ASC”) 360, Impairment or Disposal of Long-Lived Assets (“ASC 360”). When a qualifying component of the Company is disposed of or has been classified as held for sale, the operating results of that component are removed from continuing operations for all periods presented and displayed as discontinued operations if: (a) elimination of the component’s operations and cash flows from the Company’s ongoing operations has occurred (or will occur) and (b) significant continuing involvement by the Company in the component’s operations does not exist after the disposal transaction.

On December 30, 2011, we entered into an agreement to sell our aesthetics business to Cutera, Inc. The sale of the aesthetics business was completed on February 2, 2012. The operating results of our aesthetics business were therefore classified as discontinued operations, and the associated assets and liabilities were classified as discontinued

for all periods presented under the requirements of ASC 360.

Revenue Recognition.

Our revenues arise from the sale of laser consoles, delivery devices, consumables and service and support activities. Revenue from product sales is recognized upon receipt of a purchase order and product shipment provided that no significant obligations remain and collection of the receivables is reasonably assured. Shipments are generally made with Free-On-Board ("FOB") shipping point terms, whereby title passes upon shipment from our dock. Any shipments with FOB receiving point terms are recorded as revenue when the shipment arrives at the receiving point. Cost is recognized as product sales revenue is recognized. The Company's sales may include post-sales obligations for training or other deliverables. For revenue arrangements such as these, we recognize revenue in accordance with ASC 605, Revenue Recognition, Multiple-Element Arrangements. The Company allocates revenue among deliverables in multiple-element arrangements using the relative selling price method. Revenue allocated to each element is recognized when the basic revenue recognition criteria is met for each element. The Company is required to apply a hierarchy to determine the selling price to be used for allocating revenue to deliverables: (i) vendor-specific objective evidence of selling price ("VSOE"), (ii) third-party evidence of selling price ("TPE") and (iii) best estimate of the selling price ("ESP"). In general, the Company is unable to establish VSOE or TPE for all of the elements in the arrangement; therefore, revenue is allocated to these elements based on the Company's ESP, which the Company determines after considering multiple factors such as management approved pricing guidelines, geographic differences, market conditions, competitor pricing strategies, internal costs and gross margin objectives. These factors may vary over time depending upon the unique facts and circumstances related to each deliverable. As a result, the Company's ESP for products and services could change. Revenues for post-sales obligations are recognized as the obligations are fulfilled.

In international regions, we utilize distributors to market and sell our products. We recognize revenue upon shipment for sales to these independent, third-party distributors as we have no continuing obligations subsequent to shipment. Generally our distributors are responsible for all marketing, sales, installation, training and warranty labor coverage for our products. Our standard terms and conditions do not provide price protection or stock returns rights to any of our distributors.

Royalty revenues are typically based on licensees' net sales of products that utilize our technology and are recognized as earned in accordance with the contract terms when royalties from licensees can be reliably measured and collectibility is reasonably assured, such as upon the earlier of the receipt of a royalty statement from the licensee or upon payment by the licensee.

Inventories.

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

Sales Returns Allowance and Allowance for Doubtful Accounts.

The Company estimates future product returns related to current period product revenue. We analyze historical returns, and changes in customer demand and acceptance of our products when evaluating the adequacy of the sales

returns allowance. Significant management judgment and estimates must be made and used in connection with establishing the sales returns allowance in any accounting period. Material differences may result in the amount and timing of our revenue for any period if management made different judgments or utilized different estimates. Our provision for sales returns is recorded net of the associated costs. The balance for the provision of sales returns have not historically been material.

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

Warranty.

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

Income Taxes.

We account for income taxes in accordance with ASC 740, Income Taxes (“ASC 740”), which requires that deferred tax assets and liabilities be recognized using enacted tax rates for the effect of temporary differences between the book and tax bases of recorded assets and liabilities. Under ASC 740, the liability method is used in accounting for income taxes. Deferred tax assets and liabilities are determined based on the differences between financial reporting and the tax basis of assets and liabilities, and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. ASC 740 also requires that deferred tax assets be reduced by a valuation allowance if it is more likely than not that some or all of the deferred tax asset will not be realized. We evaluate annually the realizability of our deferred tax assets by assessing our valuation allowance and by adjusting the amount of such allowance, if necessary. The factors used to assess the likelihood of realization include our forecast of future taxable income and available tax planning strategies that could be implemented to realize the net deferred tax assets. In 2013 and 2012, we have recorded a full valuation allowance for our deferred tax assets based on our historical loss and the uncertainty regarding our ability to project future taxable income. In future periods if we are able to generate income we may reduce or eliminate the valuation allowance.

On September 13, 2013, the Internal Revenue Service (“IRS”) and Treasury Department released final regulations under Sections 162(a) and 263(a) of the IRC on the deduction and capitalization of expenditures related to tangible personal property (the final repair regulations). The entirety of the final repair regulations apply to the Company’s 2014 tax year. Application of these regulations is not expected to have a material impact on the Company’s consolidated financial statements.

Accounting for Uncertainty in Income Taxes.

We account for uncertain tax positions in accordance with ASC 740. ASC 740 seeks to reduce the diversity in practice associated with certain aspects of measurement and recognition in accounting for income taxes. ASC 740 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax provision that an entity takes or expects to take in a tax return. Additionally, ASC 740 provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosures, and transition. Under ASC 740, an entity may only recognize or continue to recognize tax positions that meet a "more likely than not" threshold. In accordance with our accounting policy, we recognize accrued interests and penalties related to unrecognized tax benefits as a component of income tax expense.

Accounting for Stock-Based Compensation.

The Company accounts for stock-based compensation in accordance with ASC 718, Compensation - Stock Compensation (“ASC 718”) which establishes accounting for share-based awards exchanged for employee services. Accordingly, stock-based compensation cost is measured at grant date, based on the fair value of the award, and is

recognized as expense over the employee's service period. The Company recognizes compensation expense on a straight-line basis over the requisite service period of the award.

We determined that the Black-Scholes option pricing model is the most appropriate method for determining the estimated fair value for stock options. The Black-Scholes option pricing model requires the use of highly subjective and complex assumptions which determine the fair value of share-based awards, including the option's expected term and the price volatility of the underlying stock.

Recently Issued and Adopted Accounting Standards

In February 2013, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2013-02, Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income ("AOCI"), which aims to improve the reporting of reclassifications out of AOCI. This update requires an entity to report the effect of significant reclassifications out of AOCI on the respective line items in net income if the amount being reclassified is required under US GAAP to be reclassified in its entirety to net income. For other amounts that are not required under US GAAP to be reclassified in their entirety to net income in the same reporting period, an entity is required to cross-reference other disclosures required under US GAAP that provide additional detail about those amounts. The amendments do not change the current requirements for reporting net income or other comprehensive income in financial statements. For public entities, the amendments are effective prospectively for reporting periods beginning after December 15, 2012. The Company adopted this standard in the first quarter of fiscal year 2013. The adoption of this standard did not have a material effect on our consolidated financial position, results of operations, or cash flows.

In July 2013, the FASB issued ASU No. 2013-11, Presentation of an Unrecognized Tax Benefit when a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists ("ASU 2013-11"). This standard requires an entity to present unrecognized tax benefits as a reduction to deferred tax assets when a net operating loss carryforward, similar tax loss or a tax credit carryforward exists, with limited exceptions. This standard is effective for fiscal years beginning on or after December 15, 2013, and for interim periods within those fiscal years. Since ASU 2013-11 only impacts financial statement disclosure requirements for unrealized tax benefits, the Company does not expect its adoption to have an impact on the Company's financial position or results of operations.

Off-Balance Sheet Arrangements

The Company has no off-balance sheet arrangements.

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

Market risk represents the risk of loss that may impact the financial position, results of operations or cash flows due to adverse changes in financial and commodity market prices and rates. We transact the majority of our business in US dollars and therefore changes in foreign currency rates will not have a significant impact on our income statement or cash flows. However, increases in the value of the US dollar against any local currencies could cause our products to become relatively more expensive to customers in a particular country or region, leading to reduced revenue or profitability in that country or region. As we continue to expand our international sales, our non-U.S. dollar denominated revenue and our exposure to gains and losses on international currency transactions may increase. We currently do not engage in transactions to hedge against the risk of the currency fluctuation, but we may do so in the future.

Item 8. Financial Statements and Supplementary Data.

Our consolidated balance sheets as of December 28, 2013 and December 29, 2012 and the consolidated statements of operations, comprehensive income, stockholders' equity and cash flows for each of our fiscal years 2013, 2012 and 2011 together with the related notes and the report of our independent registered public accounting firm, are on the following pages. Additional required financial information is described in Item 15.

32

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of IRIDEX Corporation

We have audited the accompanying consolidated balance sheets of IRIDEX Corporation (the "Company") as of December 28, 2013 and December 29, 2012, and the related consolidated statements of operations, comprehensive income, stockholders' equity, and cash flows for each of the three years in the period ended December 28, 2013. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of IRIDEX Corporation as of December 28, 2013 and December 29, 2012, and the results of their operations and their cash flows for each of the three years in the period ended December 28, 2013 in conformity with accounting principles generally accepted in the United States of America.

/s/ Burr Pilger Mayer, Inc

San Jose, California

March 27, 2014

IRIDEX Corporation

CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share data)

	FY 2013 December 28, 2013	FY 2012 December 29, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	$ 13,444	$ 11,901
Accounts receivable, net of allowance for doubtful accounts of $207 in 2013 and $146 in 2012	7,345	5,480
Inventories	10,605	8,035
Prepaid expenses and other current assets	576	1,129
Current assets of discontinued operations	—	510
Total current assets	31,970	27,055
Property and equipment, net	543	483
Other intangible assets, net	328	554
Goodwill	533	533
Other long-term assets	303	287
Total assets	$ 33,677	$ 28,912
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,278	$ 2,105
Accrued compensation	1,891	1,563
Accrued expenses	1,592	1,242
Accrued warranty	468	453
Deferred revenue	1,133	1,004
Total current liabilities	7,362	6,367
Long-term liabilities:		
Other long-term liabilities	461	640
Total liabilities	7,823	7,007
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Convertible preferred stock, $0.01 par value:		
Authorized: 2,000,000 shares;		
Issued and outstanding: 0 and 500,000 shares in 2013 and 2012, respectively;		
Liquidation preference of $5,000 in 2012	—	5
Common stock, $0.01 par value:		
Authorized: 30,000,000 shares;		
Issued and outstanding: 9,899,483 shares in 2013 and 8,452,971 shares in 2012	104	94

Additional paid-in capital	40,671	38,958
Accumulated deficit	(14,921)	(17,152)
Total stockholders' equity	25,854	21,905
Total liabilities and stockholders' equity	$ 33,677	$ 28,912

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

IRIDEX Corporation

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

	FY 2013 Year Ended December 28, 2013	FY 2012 Year Ended December 29, 2012	FY 2011 Year Ended December 31, 2011
Total revenues	$ 38,273	$ 33,859	$ 33,159
Cost of revenues	19,686	17,513	16,869
Gross profit	18,587	16,346	16,290
Operating expenses:			
Research and development	3,684	4,385	3,913
Sales and marketing	7,720	7,895	7,458
General and administrative	5,023	4,926	4,259
Proceeds from demutualization of insurance carrier	(473)	—	—
Legal settlement, net of expenses	—	—	(1,274)
Total operating expenses	15,954	17,206	14,356
Income (loss) from continuing operations	2,633	(860)	1,934
Legal settlement	—	800	800
Interest and other expense, net	(371)	(210)	(296)
Income (loss) from continuing operations before provision (benefit from) income taxes	2,262	(270)	2,438
Provision for (benefit from) income taxes	31	(100)	297
Income (loss) from continuing operations, net of tax	2,231	(170)	2,141
Income (loss) from discontinued operations, net of tax	—	(264)	469
Gain on sale of discontinued operations, net of tax	—	1,872	—
Income from discontinued operations, net of tax	—	1,608	469
Net income	$ 2,231	$ 1,438	$ 2,610
Net income (loss) per share:			
Basic -			
Continuing operations	$ 0.24	$ (0.02)	$ 0.24
Discontinued operations	0.00	0.18	0.05
Net income	$ 0.24	$ 0.16	$ 0.29

Diluted -

Continuing operations	$ 0.22	$ (0.02)	$ 0.21
Discontinued operations	0.00	0.18	0.05
Net income	$ 0.22	$ 0.16	$ 0.26
Weighted average shares used in computing net income per common share - basic	9,245	8,935	8,958
Weighted average shares used in computing net income per common share - diluted	10,104	8,935	10,225

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

IRIDEX Corporation

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(in thousands)

	FY 2013 Year Ended December 28, 2013	FY 2012 Year Ended December 29, 2012	FY 2011 Year Ended December 31, 2011
Net income	$ 2,231	$ 1,438	$ 2,610
Other comprehensive income, net of tax:			
Recognition of accumulated foreign currency translation loss	—	35	170
Other comprehensive income, net of tax	—	35	170
Comprehensive income	$ 2,231	$ 1,473	$ 2,780

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

IRIDEX Corporation

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in thousands, except share data)

	Convertible Preferred Stock		Common Stock		Additional		Accumulated Other		
	Shares	Amount	Shares	Amount	Paid-in Capital	Treasury Stock	Comprehensive Income (Loss)	Accumulated Deficit	Total
FY 2010: Balances, January 1, 2011	500,000	$ 5	8,986,418	$ 89	$ 41,168	$ (430)	$ (205)	$ (21,200)	$ 19,427
Issuance of common stock under stock option plan			99,291	1	320				321
Employee stock-based compensation expense					544				544
Tax effect of stock compensation expense					2				2
Foreign currency translation adjustments							170		170
Issuance of common stock in connection with RetinaLabs acquisition				2	(2)				—
Stock repurchase			(167,885)			(648)			(648)
Net income								2,610	2,610
FY 2011: Balances, December 31, 2011	500,000	5	8,917,824	92	42,032	(1,078)	(35)	(18,590)	22,426
Issuance of common stock under stock option plan			174,631	2	443				445

Employee stock-based compensation expense					396				396
Release of restricted stock and escrow shares			36,815						
Stock repurchase			(188,799)			(734)			(734)
Stock repurchased from tender offer			(487,500)		(2,101)				(2,101)
Retirement of treasury stock					(1,812)	1,812			—
Foreign currency translation adjustments							35		35
Net income								1,438	1,438
FY 2012: Balances, December 29, 2012	500,000	5	8,452,971	94	38,958	—	—	(17,152)	21,905
Issuance of common stock under stock option plan			493,622	5	1,490				1,495
Employee stock-based compensation expense					689				689
Release of restricted stock and escrow shares			27,915						—
Stock repurchase			(75,025)		(426)				(426)
Stock repurchased from tender offer					(40)				(40)
Preferred stock conversion to common stock	(500,000)	(5)	1,000,000	5					—
Net income								2,231	2,231
	—	$ —	9,899,483	$ 104	$ 40,671	$—	$ —	$ (14,921)	$25,854

FY 2013: Balances, December 28, 2013	

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

TIRIDEX Corporation

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	FY 2013 Year Ended December 28, 2013	FY 2012 Year Ended December 29, 2012	FY 2011 Year Ended December 31, 2011
Operating activities:			
Net income	$ 2,231	$ 1,438	$ 2,610
Less income from discontinued operations	—	1,608	469
Income (loss) from continuing operations	2,231	(170)	2,141
Adjustments to reconcile net income (loss) from continuing operations to net cash provided by (used in) operating activities:			
Depreciation and amortization	490	427	410
Change in fair value of earn-out liability	355	215	280
Stock-based compensation cost recognized	689	388	478
Tax effect of stock compensation expense	—	—	2
Provision for doubtful accounts	61	33	(12)
Changes in operating assets and liabilities, net of assets and liabilities acquired:			
Accounts receivable	(1,926)	38	(82)
Inventories	(2,514)	(1,376)	(1,027)
Prepaid expenses and other current assets	553	(665)	(75)
Other long-term assets	(16)	(88)	7
Accounts payable	173	525	66
Accrued compensation	328	383	(209)
Accrued expenses	171	(756)	285
Accrued warranty	15	(103)	(51)
Deferred revenue	129	(10)	12
Other long-term liabilities	28	21	26
Net cash provided (used in) by operating activities	767	(1,138)	2,251
Investing activities:			
Acquisition of property and equipment	(380)	(394)	(203)
Cash paid in business combination	—	—	(75)
Payment on earn-out liability	(383)	(328)	—
Net cash used in investing activities	(763)	(722)	(278)
Cash flows from financing activities:			
Proceeds from stock option exercises	1,495	445	321
Repurchase of common stock	(426)	(2,835)	(648)
Payment of legal costs in connection with tender offer	(40)	—	—

Net cash provided by (used in) financing activities	1,029	(2,390)	(327)
Net cash provided by operating activities from discontinued operations	—	695	797
Net cash provided by investing activities from discontinued operations	510	4,632	—
Effect of foreign exchange rate changes from discontinued operations	—	35	(1)
Net cash provided by discontinued operations	510	5,362	796
Net increase in cash and cash equivalents	1,543	1,112	2,442
Cash and cash equivalents, beginning of year	11,901	10,789	8,347
Cash and cash equivalents, end of year	$ 13,444	$ 11,901	$ 10,789
Supplemental disclosure of cash flow information:			
Cash paid (received) during the year for:			
Income taxes	$ (536)	$ (145)	$ 522
Interest paid	$ —	$ —	$ 1
Supplemental disclosure of non-cash activities:			
Contingent consideration – earn-out liability	$ —	$ —	$ 105
Conversion of preferred stock to common stock	$ 5	$ —	$ —

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

IRIDEX Corporation

Notes to Consolidated Financial Statements

1. Organization

Description of Business.

IRIDEX Corporation ("IRIDEX", the "Company", "we", "us", or "our") is a leading worldwide provider of therapeutic based laser systems, delivery devices and consumable instrumentation used to treat sight-threatening eye diseases in ophthalmology. Our ophthalmology products are sold in the United States ("U.S.") predominantly through a direct sales force, and an independent sales force, and internationally through approximately 70 independent distributors in over 100 countries. In February 2012, we completed the sale of our aesthetics business to Cutera, Inc. and reclassified the aesthetics business segment as discontinued operations.

2. Summary of Significant Accounting Policies

Financial Statement Presentation.

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

Our fiscal year always ends on the Saturday closest to December 31. Fiscal 2013 ended on December 28, 2013, fiscal 2012 ended on December 29, 2012, and fiscal 2011 ended on December 31, 2011. Each fiscal year consisted of 52 weeks of operations.

Reclassifications.

In February 2012, we completed the sale of our aesthetics business to Cutera, Inc. In accordance with accounting principles generally accepted in the U.S. ("GAAP"), we have recast our financial information to show the results from our ophthalmology business as continuing operations and the results from our aesthetics business as discontinued operations.

Use of Estimates.

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

Discontinued Operations.

Discontinued operations are accounted for and presented in accordance with Accounting Standards Codification ("ASC") 360, Impairment or Disposal of Long-Lived Assets, ("ASC 360"). When a qualifying component of the Company is disposed of or has been classified as held for sale, the operating results of that component are removed from continuing operations for all periods presented and displayed as discontinued operations if: (a) elimination of the component's operations and cash flows from the Company's ongoing operations has occurred (or will occur) and (b) significant continuing involvement by the Company in the component's operations does not exist after the disposal transaction.

On December 30, 2011, we entered into an agreement to sell our aesthetics business to Cutera, Inc. The operating results of our aesthetics business were therefore classified as discontinued operations, and the associated assets and liabilities were classified as discontinued operations for all periods presented under the requirements of ASC 360. The sale of the aesthetics business was completed on February 2, 2012.

(in thousands)	FY 2013 Year Ended December 28, 2013	FY 2012 Year Ended December 29, 2012	FY 2011 Year Ended December 31, 2011
Total revenues	$ —	$ 1,630	$ 10,840
Income (loss) from discontinued operations	$ —	$ (325)	$ 653
Gain on sales of aesthetics business	$ —	$ 1,149	$ —
Income from discontinued operations, before income taxes	$ —	$ 824	$ 653
Income tax (benefit) expense	$ —	$ (784)	$ 184
Income from discontinued operations, net of tax	$ —	$ 1,608	$ 469

Current assets of discontinued operations as of December 29, 2012 comprised of restricted cash in the amount of $510 thousand. In accordance with the terms of the sale of the aesthetics segment to Cutera, Inc., 10% of the total purchase price was deposited and held in an escrow account for a period of twelve months from the date of closing and was available to resolve certain claims by Cutera, Inc., if any, against which the Company had indemnified Cutera, Inc. There had been no claims made by Cutera, Inc. and in May 2013, the cash held in the escrow account was released to the Company.

Cash and Cash Equivalents.

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

Sales Returns Allowance and Allowance for Doubtful Accounts.

The Company estimates future product returns related to current period product revenue. We analyze historical returns, and changes in customer demand and acceptance of our products when evaluating the adequacy of the sales returns allowance. Significant management judgment and estimates must be made and used in connection with establishing the sales returns allowance in any accounting period. Material differences may result in the amount and timing of our revenue for any period if management made different judgments or utilized different estimates. Our provision for sales returns is recorded net of the associated costs. The balance for the provision of sales returns was $33 thousand and $53 thousand as of December 28, 2013 and December 29, 2012, respectively, and is recorded within the deferred revenue accounts in the balance sheet.

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

Inventories.

Inventories are stated at the lower of cost or market and include on-hand inventory physically held at the Company’s facility, sales demo inventory and service loaner inventory. Cost is determined on a standard cost basis which approximates actual cost on a first-in, first-out (“FIFO”) method. Lower of cost or market is evaluated by considering

obsolescence, excessive levels of inventory, deterioration and other factors. Adjustments to reduce the cost of inventory to its net realizable value, if required, are made for estimated excess, obsolescence or impaired inventory and are charged to cost of revenues. Once the cost of the inventory is reduced, a new lower-cost basis for that inventory is established, and subsequent changes in facts and circumstances do not result in the restoration or increase in that newly established cost basis. Factors influencing these adjustments include changes in demand, product life cycle and development plans, component cost trends, product pricing, physical deterioration and quality issues. Revisions to these adjustments would be required if these factors differ from our estimates.

As part of our normal business, we generally utilize various finished goods inventory as either sales demos to facilitate the sale of our products to prospective customers, or as loaners that we allow our existing customers to use while we repair their products. The Company is amortizing these demos and loaners over an estimated useful life of four years. The amortization of the demos is charged to sales expense while the amortization on the loaners is charged to cost of revenues. The gross value of demos and loaners was $1.6 million and $1.4 million and the accumulated amortization was $601 thousand and $603 thousand as of December 28, 2013 and December 29, 2012, respectively. The net book value of demos and loaners is charged to cost of revenues when such demos or loaners are sold.

Property and Equipment.

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

Valuation of Goodwill and Intangible Assets.

Goodwill represents the excess of the purchase price over the fair value of the net tangible and identifiable intangible assets acquired in a business combination. The Company reviews goodwill for impairment on an annual basis or whenever events or changes in circumstances indicate the carrying value may not be recoverable. The Company first assesses qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step quantitative goodwill impairment test. If, after assessing the totality of circumstances, an entity determines that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, then it is required to perform the two-step impairment test. It does not require an entity to calculate the fair value of a reporting unit unless the entity determines that it is more likely than not that its fair value is less than its carrying value. However, an entity also has the option to bypass the qualitative assessment for any reporting unit in any period and proceed directly to performing the first step of the two-step goodwill impairment test. The Company has determined that it has a single reporting unit for purposes of performing its goodwill impairment test. As the Company uses the market approach to assess impairment, its common stock price is an important component of the fair value calculation. If the Company's stock price continues to experience significant price and volume fluctuations, this will impact the fair value of the reporting unit and can lead to potential impairment in future periods. The Company performed its annual impairment test during the second quarter of 2013 and determined that its goodwill was not impaired. As of December 28, 2013, the Company had not identified any factors that indicated there was an impairment of its goodwill and determined that no additional impairment analysis was then required.

Intangible assets with definite lives are amortized over the useful life of the asset. We review our amortizing intangible assets for impairment whenever events or changes in circumstances indicate that their carrying value may not be recoverable. An asset is considered impaired if its carrying amount exceeds the future non-discounted net cash flow the asset is expected to generate. If an asset is considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds its fair value. In such circumstances, the Company conducts an impairment analysis in accordance with the Impairment or Disposal of Long-Lived Assets Section of ASC 360, Property, Plant and Equipment. See Note 8 – Intangible Assets.

Revenue Recognition.

Our revenues arise from the sale of laser consoles, delivery devices, consumables and service and support activities. Revenue from product sales is recognized upon receipt of a purchase order and product shipment provided that no significant obligations remain and collection of the receivables is reasonably assured. Shipments are generally made with Free-On-Board ("FOB") shipping point terms, whereby title passes upon shipment from our dock. Any shipments with FOB receiving point terms are recorded as revenue when the shipment arrives at the receiving point. Cost is recognized as product sales revenue is recognized. The Company's sales may include post-sales obligations for training or other deliverables. For revenue arrangements such as these, we recognize revenue in accordance with ASC 605, Revenue Recognition, Multiple-Element Arrangements. The Company allocates revenue among deliverables in multiple-element arrangements using the relative selling price method. Revenue allocated to each element is recognized when the basic revenue recognition criteria is met for each element. The Company is required to apply a hierarchy to determine the selling price to be used for allocating revenue to deliverables: (i) vendor-specific objective

evidence of selling price (“VSOE”), (ii) third-party evidence of selling price (“TPE”) and (iii) best estimate of the selling price (“ESP”). In general, the Company is unable to establish VSOE or TPE for all of the elements in the arrangement; therefore, revenue is allocated to these elements based on the Company’s ESP, which the Company determines after considering multiple factors such as management approved pricing guidelines, geographic differences, market conditions, competitor pricing strategies, internal costs and gross margin objectives. These factors may vary over time depending upon the unique facts and circumstances related to each deliverable. As a result, the Company’s ESP for products and services could change. Revenues for post-sales obligations are recognized as the obligations are fulfilled.

In international regions, we utilize distributors to market and sell our products. We recognize revenue upon shipment for sales to these independent, third-party distributors as we have no continuing obligations subsequent to shipment. Generally our distributors are responsible for all marketing, sales, installation, training and warranty labor coverage for our products. Our standard terms and conditions do not provide price protection or stock return rights to any of our distributors.

Royalty revenues are typically based on licensees' net sales of products that utilize our technology and are recognized as earned in accordance with the contract terms when royalties from licensees can be reliably measured and collectibility is reasonably assured, such as upon the earlier of the receipt of a royalty statement from the licensee or upon payment by the licensee.

Taxes Collected from Customers and Remitted to Governmental Authorities.

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

Deferred Revenue.

Revenue related to service contracts is deferred and recognized on a straight line basis over the period of the applicable service period. Costs associated with these service arrangements are recognized as incurred. A reconciliation of the changes in the Company's deferred revenue balances for the years ended December 28, 2013 and December 29, 2012 are as follows (in thousands):