

IRIDEX CORP  
Form 10-K  
March 30, 2012  
Table of Contents

**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 31, 2011

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**  
(State or other jurisdiction  
of incorporation or organization)

**77-0210467**  
(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:**

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Title of Each Class	Name of Each Exchange on which Registered
Common	NASDAQ Global Market

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

**Common Stock, par value \$0.01 per share**

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

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

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

Indicate by check mark whether the registrant has submitted electronically 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  No

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

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, 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

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

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The aggregate market value of the voting common equity held by non-affiliates of the Registrant was approximately \$18,290,400 as of June 30, 2011 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 21, 2012, Registrant had 8,942,483 shares of common stock outstanding.

### **DOCUMENTS INCORPORATED BY REFERENCE**

Certain parts of the Proxy Statement for the Registrant's 2012 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****Table of Contents**

	<b>Page No.</b>
<u>Part I</u>	
Item 1. <u>Business</u>	3
Item 1A. <u>Risk Factors</u>	13
Item 1B. <u>Unresolved Staff Comments</u>	23
Item 2. <u>Properties</u>	23
Item 3. <u>Legal Proceedings</u>	23
Item 4. <u>Mine Safety Disclosures</u>	23
<u>Part II</u>	
Item 5. <u>Market for Registrant's Common Equity and Related Stockholder Matters, and Issuer Purchases of Equity Securities</u>	24
Item 6. <u>Selected Financial Data</u>	25
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	25
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	31
Item 8. <u>Financial Statements and Supplementary Data</u>	31
Item 9. <u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	55
Item 9A. <u>Controls and Procedures</u>	55
Item 9B. <u>Other Information</u>	56
<u>Part III</u>	
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	57
Item 11. <u>Executive Compensation</u>	57
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	57
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	57
Item 14. <u>Principal Accountant Fees and Services</u>	57
<u>Part IV</u>	
Item 15. <u>Exhibits, Financial Statement Schedules and Reports on Form 8-K</u>	58
<u>Signatures</u>	62

**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; 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, potential, 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.*

**Item 1. Business**  
**General**

IRIDEX Corporation is a leading worldwide provider of therapeutic based laser systems, delivery devices and consumable instrumentation used to treat sight-threatening eye diseases in ophthalmology. On December 30, 2011 we entered into an agreement to sell our aesthetics business to Cutera, Inc. In accordance with US 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. We announced the closing of the transaction on February 3, 2012. 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 2011, 2010 and 2009 were \$33.2 million, \$32.3 million and \$31.0 million, respectively and we generated net income from continuing operations of \$2.1 million, \$1.7 million and \$1.5 million respectively. Total net income including income from discontinued operations for 2011, 2010 and 2009 was \$2.6 million, \$3.0 million and \$2.6 million, respectively.

Our ophthalmology products consist of laser systems, 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. Therefore our ophthalmology business includes (i) a recurring revenue component, consisting of sales of consumable, predominantly single use laser probe devices and other instrumentation, combined with the repair, servicing and extended service contract protection for our laser systems and (ii) a capital component, which consists of the laser systems combined with durable delivery devices.

Our laser systems 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 Symphony (Laser Delivery System), OcuLight SL, OcuLight SLx, OcuLight GL and OcuLight GLx laser photocoagulation systems.

Ophthalmologists typically use our laser systems in hospital operating rooms ( OR ) and ambulatory surgical centers ( ASC ), as well as their offices and clinics. In the OR and ASC, 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.



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## **Table of Contents**

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](http://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 UK, 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 World Health Organization Vision 2020 The Right to Sight 2007 report (WHO) at least 171 million people worldwide have diabetes, and this figure is likely to more than double by the year 2030. According to the WHO, 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 *see Item 1 Business: Ophthalmology Treatments, for use of our products in treating diabetic retinopathy*. 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 a few months to be fully effective and have been demonstrated to last for many years. This treatment presents a very cost efficient model, but the patient risks the possibility of losing visual function to varying degrees. Pharmaceuticals can result in stabilization of 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 pharmaceuticals require repeated injections in the eye, which are painful to the patient, increases the chances of adverse side effects, are costly, and the long term viability of pharmaceuticals is unproven. The short comings in treating this disease have lead to a renewed interest in investigating alternative approaches that might result in better patient outcomes.

Age-related macular degeneration (AMD) is a disease that affects the aged. WHO indicates that in 2006 3 million persons had lost their site 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. Similar to pharmaceuticals used for the treatment of diabetic retinopathy patients receiving pharmaceutical treatment for AMD are required to be injected in the eye every six to eight weeks. 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. Continuous wavelength laser photocoagulation can also be used to treat AMD and, although the treatment can have a beneficial therapeutic impact, 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 *see Item 1 Business: Ophthalmology Treatments, for use of our products in treating AMD*. The short comings in treating this disease has lead to a renewed interest in investigating alternative approaches that might allow treatment earlier which would result in better patient outcomes.

Glaucoma is a leading cause of blindness in the world. WHO estimates that about 60.5 million people have glaucoma in 2010 and given the aging of the world's population, this number may increase to almost 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 remainder 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 fail to appropriately apply the medication in their eye or to apply the medication on time, which significantly reduces the effectiveness of the pharmaceutical. Even when administered correctly, pharmaceuticals have demonstrated that their efficacy is reduced over time. When pharmaceuticals lose their effectiveness, laser treatment is often performed, and ultimately surgery may be required *see Item 1 Business: Ophthalmology Treatments, for use of our products in treating Glaucoma*. The short comings in treating this disease have lead to a renewed interest in surgical approaches that might result in better patient outcomes.

### **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 serious eye diseases. Over the last three years we have executed a turnaround strategy and rebuilt the financial strength of the Company. At the end of 2011, the Company had \$10.8 million in cash, no debt and had been profitable for the last three years. With the sale of our aesthetics business we can now focus exclusively on our ophthalmology business.

Our strategy is to leverage the existing brand and distribution channel of IRIDEX in the ophthalmology market 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.
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.*

### **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 used 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.

We have developed a new method of performing laser photocoagulation using a mode which chops the CW beam into short (microsecond long) laser pulses, which we call MicroPulse mode. Studies have demonstrated that MicroPulse therapy can generate the beneficial response associated with CW laser photocoagulation with no detectible tissue damage. We refer to this as tissue sparing laser photocoagulation which preserves visual function.

### **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 equipment products range in price from \$2,000 to \$50,000 and consist of laser consoles and specialized durable delivery devices. Our line of consumable products range in price from \$20 to \$210 and consist primarily of cannulas and laser probes.



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## **Table of Contents**

### **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.* In 2009 we introduced the industry's first solid state 577nm (yellow) photocoagulator - the IQ 577. This product utilizes state of the art user interface technology and delivers a 577 wavelength which is at the peak of oxyhemoglobin absorption which 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 Consoles.* We have a family of solid state and semiconductor-based photocoagulator consoles used in ophthalmology delivering visible (Green 532nm) laser light. In 2010 we introduced the IQ 532nm photocoagulator. This product utilizes the 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 requires 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.

*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.

*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.* 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.



**Table of Contents**

*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 (more than one 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 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.

**Table of Contents****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, ASC or clinic and are non-elective and covered by insurance.

	<b>Procedure</b>	<b>Console</b>	<b>Delivery Devices and Other Product</b>	<b>Mode</b>
Age-related Macular Degeneration	Retinal Photocoagulation	Infrared & Visible	Slit Lamp Adapter	CW
Diabetic Retinopathy	Grid Retinal Photocoagulation	Infrared & Visible	Slit Lamp Adapter & Operating Microscope Adapter,	CW or MicroPulse
Macular Edema	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 research and development ( R&D ) activities are performed by a current team of 14 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 research and development process integrates all

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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.

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## **Table of Contents**

Our research activities are managed internally by our research staff. We supplement our internal research 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 age-related macular degeneration, diabetic retinopathy and glaucoma. 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 \$3.9 million on research and development in our continuing operations in 2011, \$3.8 million in 2010 and \$3.3 million in 2009.

We consider clinical projects to be a component of our research and development 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 to ophthalmologists specializing in retina, glaucoma and pediatrics. Other customers include research and teaching hospitals, government installations, surgical centers and hospitals. No single customer or distributor accounted for 10% or more of total sales in fiscal years 2011, 2010 and 2009.

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 almost anywhere in the world.

## **Sales and Marketing**

We sell and market our products in the United States predominantly through our direct sales force and internationally through approximately 70 independent distributors into over 100 countries. Currently we have a direct sales force of 12 employees who were engaged in sales efforts within the United States and 4 employees engaged in managing our distribution sales efforts internationally. 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 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 44.4%, 44.8% and 42.1% of our sales in 2011, 2010 and 2009, 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 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.*

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## **Table of Contents**

In the past, we maintained two wholly owned subsidiaries, one located in the United Kingdom (UK) and the other in the France, both 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 in February 2012, we transitioned the responsibility for the sales and service of our aesthetics products in France to Cutera, Inc. We do not currently maintain any operating subsidiaries.

To support our sales process we conduct marketing programs which include: clinical education, direct mail, 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 unmet 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.

## **Operations**

The manufacture of our visible light and infrared photocoagulators 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 41 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**

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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: product performance, clinical outcomes, ease of use, durability, versatility, customer training services and rapid repair of equipment.



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## **Table of Contents**

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) and to a lesser extent Visudyne (Novartis), Macugen (OSI Pharmaceuticals) and Osurdex (Allergan) 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 others such as RetinaLabs or OcuNetics. We file patent applications to protect technology, inventions and improvements that are significant to the development of our business. We have been issued twenty eight United States patents and fifteen foreign patents on the technologies related to our continuing products and processes, which have expiration dates ranging from 2013 to 2028. We have approximately three pending patent applications in the United States and six 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

## **Table of Contents**

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.

Exports of our products are regulated by the FDA and are 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 for 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



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## **Table of Contents**

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 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 Changes in Third Party Coverage and Reimbursement Policies and any Uncertainty Regarding Healthcare Reform Measures.*

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**

We generally do not maintain a high level of backlog. As a result, we do not believe that our backlog at any particular time is indicative of future sales levels.

### **Employees**

Currently, we have a total of 106 full-time equivalent employees engaged in our ongoing ophthalmology operations, including 50 in operations and service, 26 in sales and marketing, 16 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 31, 2011, we employed 27 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, on our website at [www.IRIDEX.com](http://www.IRIDEX.com), as soon as reasonably practicable after such reports are electronically filed with the Securities and Exchange Commission, however, the

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information on, or that can be accessed through, our website is not part of this report. Additionally, these filings may also be accessed through the SEC's website at [www.sec.gov](http://www.sec.gov). Further, a copy of this Annual Report on Form 10-K is located at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330.

## **Table of Contents**

### **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 operation. You should carefully consider the risks described below before making an investment decision.

#### *We Recently Sold our Aesthetics Business Unit and Therefore Our Operating Results Will Be Adversely Affected in the Near Term*

In December 2011, we announced the sale of our aesthetics business and the transaction closed in February 2012. Prior to the sale, our aesthetics business covered its direct costs and therefore contributed to the profitability of the overall company. The sale of the aesthetics business means that we will need to adjust our cost structure and/or grow revenues from our continuing ophthalmology business to remain profitable. In addition, we provided the purchaser typical indemnification provisions associated with this type of transaction, and there is a risk that an adverse event may occur that requires us to fulfill our indemnity obligation. In the near term these factors will have a material adverse effect on our business, financial condition and results of operations.

#### *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 between ophthalmology products and foreign and domestic sales;

our ability to address our liquidity issues should the need occur;

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, 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;

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**Table of Contents**

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. In addition, the trading price of our common stock has been significantly adversely affected by our recent operating performance and by liquidity issues. For fiscal year 2011, the trading price of our common stock fluctuated from a low of \$3.15 per share to a high of \$4.65 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;

recommendations and opinions by ophthalmologists, other clinicians, and their associated opinion leaders;

clinical study outcomes;

price of our products and prices of competing products and technologies particularly in light of the current macro-economic environment where healthcare systems and healthcare operators are becoming increasingly price sensitive;

availability of competing products, technologies and alternative treatments; and

level of reimbursement for treatments administered with our products.

In addition, we derive a meaningful portion of our sales in the form of recurring revenues from selling consumable instrumentation including our EndoProbe devices and service. Our ability to increase recurring revenues from the sale of consumable products will depend primarily upon the



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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.

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**Table of Contents**

*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), and to a lesser extent Visudyne (Novartis), Macugen (OSI Pharmaceuticals) and Osurdex (Allergan) 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 challenging 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 31, 2011, our international ophthalmology sales were \$14.7 million or 44.4% of total sales. 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 international conflicts, terrorist and military activity, civil unrest;

impact of recessions in global economies and availability of credit;

fluctuations in foreign currency exchange rates;

performance of our international channel of distributors;



**Table of Contents**

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;

foreign certification requirements, including continued ability to use the CE mark in Europe, and other local regulatory requirements;

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 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.

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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.

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## **Table of Contents**

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.

*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 are seeking to acquire additional 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 additional acquisitions depends upon our ability to identify, negotiate, complete and integrate suitable acquisitions and to obtain any necessary financings. These additional efforts could divert the attention of our management and key personnel from our business operations. If we complete additional 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, additional 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 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.*

Our ability to sell our products and generate revenues depends upon our direct sales force within the United States and relationships with independent distributors outside the United States. Currently our direct sales force consists of 12 employees focused on ophthalmology and we maintain relationships with approximately 70 independent distributors internationally selling our products into over 100 countries. 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 terms of its distribution agreement 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.



## **Table of Contents**

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 limit our revenues and our ability to maintain market share. The loss of the services of these key personnel would harm our business. Similarly, our distributor agreements are generally terminable at will by either party and distributors may terminate their relationships with us, which would affect our international sales and results of operations.

### *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 twenty eight United States patents and fifteen foreign patents on the technologies related to our products and processes. We have approximately three pending patent applications in the United States and six foreign pending patent applications that have been filed. Our patent applications may not be approved. The acquisition of the RetinaLabs assets included five additional patents. 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. For example our Connector Patent used to connect our delivery devices (consumable & durable) to our laser consoles expired in 2010. Delivery devices which do not utilize our Connector Patent technology are not recognized by our laser consoles. We derive, and expect to continue to derive, a large portion of our recurring revenue and profits from sales of our consumable EndoProbe devices. Expiration of this patent may increase competition from our competitors for our consumable EndoProbe device business and there can be no guarantees that we will maintain our market share of this business.

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. For example, during fiscal year 2007, the Company settled patent litigations with Synergetics, Inc., which was time-consuming, costly and a diversion of technical and management personnel. 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.



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## **Table of Contents**

### *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.

### *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. Because of 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.

### *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. We incur substantial expense for, and devote significant time to, clinical 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 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.



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## **Table of Contents**

### *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 that may discontinue their operations 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 .

### *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 collaborate with Bausch & Lomb to design and manufacture a solid-state green wavelength (532nm) laser photocoagulator module for Bausch & Lomb, called the Millennium Endolase module. The Millennium Endolase module is designed to be a component of Bausch & Lomb's ophthalmic surgical suite product offering and is not expected to be sold as a stand-alone product. Sales of the Millennium Endolase module are dependent upon the actual order rate from and shipment rate to Bausch & Lomb, which depends on the efforts of our partner and is beyond our control. 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 sales to 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.

### *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.



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## **Table of Contents**

### *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 Federal Food, Drug and Cosmetic 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.

### *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



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**Table of Contents**

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 preceding 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.

*Because We Do Not Require Training for Users of Our Products, and Sell Our Products to Non-physicians, There Exists an Increased Potential for Misuse of Our Products, Which Could Harm Our Reputation and Our Business.*

Federal regulations restrict the sale of our products to or on the order of licensed practitioners. The definition of licensed practitioners varies from state to state. As a result, our products may be purchased or operated by physicians with varying levels of training, and in many states by non-physicians, including nurse practitioners and technicians. Outside the United States, many jurisdictions do not require specific qualifications or training for purchasers or operators of our products. We do not supervise the procedures performed with our products, nor do we require that direct medical supervision occur. We, and our distributors, generally offer but do not require purchasers or operators of our products to attend training sessions. In addition, we sometimes sell our systems to companies that rent our systems to third parties and that provide a technician to perform the procedure. The lack of training and the purchase and use of our products by non-physicians may result in product misuse and adverse treatment outcomes, which could harm our reputation and expose us to costly product liability litigation.

*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 will 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.

## **Table of Contents**

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.

### **Item 1B. Unresolved Staff Comments**

None.

### **Item 2. Properties**

We lease 37,000 square feet of space in Mountain View, California. This facility is being substantially utilized for all of our manufacturing, research and development efforts and also serves as our corporate headquarters. This facility is utilized for both our ophthalmology medical device segment and our dermatology medical device segment. We also leased 1,722 square feet facility in Lisses, France that is used for sales,



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service and support. In February 2012, this lease was assigned to Cutera Inc as part of the sale of our aesthetics business. On December 14, 2009, we terminated our lease at Cwmbran, South Wales.

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. We believe there is no litigation currently pending that could have, individually or in the aggregate, a material adverse effect on our operations or financial condition.

### **Item 4. Mine Safety Disclosures**

Not applicable.

**Table of Contents****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 has been quoted on the NASDAQ Global Market under the symbol **IRIX** and has been since our initial public offering on February 15, 1996. 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
<b>Fiscal 2011</b>		
Fourth Quarter	\$ 3.80	\$ 3.15
Third Quarter	\$ 4.10	\$ 3.48
Second Quarter	\$ 4.55	\$ 3.58
First Quarter	\$ 4.65	\$ 3.48
<b>Fiscal 2010</b>		
Fourth Quarter	\$ 3.96	\$ 3.30
Third Quarter	\$ 4.01	\$ 2.77
Second Quarter	\$ 4.50	\$ 3.65
First Quarter	\$ 4.49	\$ 2.90

On March 19, 2012 the closing price on the NASDAQ Global Market for our common stock was \$4.25 per share. As of March 19, 2012, there were approximately 61 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. In addition, the payment of cash dividends to our stockholders is currently prohibited by our credit facility. See Note 10 - Bank Borrowings, in Notes to Consolidated Financial Statements.

**Recent Sales of Unregistered Securities**

The following table provides information with respect to acquisitions by the Company of shares of its common stock during the quarter ended December 31, 2011.

**ISSUER PURCHASES OF EQUITY SECURITIES**

Period	Total Number of Shares Purchased (1)	Average Price Paid per Share (2)
10/2/11 to 11/5/11	60	\$ 0.00
11/6/11 to 12/3/11	7,909	\$ 3.74
12/4/11 to 12/31/11	26,100	\$ 3.73
Total	34,009	\$ 3.73



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**Table of Contents**

- (1) On May 5, 2011, the Board of Directors of the Company authorized a share repurchase program for an aggregate amount up to \$2.0 million of its outstanding shares of common stock. Each repurchase was financed by available cash balances and cash from operations. In March 2012, the Company announced an extension of the share repurchase program through May 2013 and an increase in the amount of cash available for the program to a total of \$4 million.
  
- (2) Average price paid per share of common stock repurchased is 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 systems, delivery devices and consumable instrumentation used to treat eye diseases in ophthalmology. In December 2011 we entered into an agreement to sell our aesthetics business to Cutera, Inc. and the transaction subsequently closed in February 2012. The Company views this as a significant step forward in its strategy because it allows the Company to focus solely on its ophthalmology business which is its 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 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 and 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.

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 - 2011, 2010 and 2009**

Our fiscal year ends on the Saturday closest to December 31. Fiscal 2011 ended on December 31, 2011, fiscal 2010 ended on January 1, 2011, and fiscal 2009 ended on January 2, 2010. Consequently, fiscal years 2011, 2010 and 2009 included 52 weeks of operations.



**Table of Contents**

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

	Percentage of Revenue Years Ended		
	FY		
	2011 Dec 31, 2011	FY 2010 Jan 1, 2011	FY 2009 Jan 2, 2010
<b>Revenues:</b>			
Total revenues	100.0%	100.0%	100.0%
Cost of revenues	50.9	49.9	50.2
Gross margin	49.1	50.1	49.8
<b>Operating expenses:</b>			
Research and development	11.8	11.6	10.7
Sales and marketing	22.4	21.9	21.1
General and administrative	12.8	12.9	14.0
Legal settlement, net of expenses	(3.8)	0.0	0.0
Total operating expense	43.2	46.4	45.8
Income from operations	5.9	3.7	4.0
Legal settlement	2.4	2.5	2.5
Interest and other expense, net	(0.9)	(0.1)	(0.7)
Total other income, net	1.5	2.4	1.8
Income from continuing operations before income taxes	7.4	6.1	5.8
Provision for income taxes	(0.9)	1.0	0.8
Income from continuing operations	6.5	5.1	5.0
Income from discontinued operations, net of tax	1.4	4.3	3.3
Net income	7.9%	9.4%	8.3%

**Comparison of 2011 and 2010***Revenues.*

Total revenues from continuing operations for 2011 were \$33.2 million compared with \$32.3 million in 2010, an increase of \$0.9 million or 2.8%. Our ophthalmology system revenues grew as a result of a resurgence in appreciation of the benefits of laser photocoagulation as a treatment modality amongst physicians and a recovery in capital spending particularly in the U.S. Competition for consumable products remains strong with increased price sensitivities amongst customers. Our OEM revenue is generated from a long standing relationship, the product is now in end of life and demand has and will continue to decline.

(in millions)	FY 2011	FY 2010	Change in \$	Change in %
Ophthalmology systems - domestic	\$ 7.2	\$ 6.2	\$ 1.0	16.1%
Ophthalmology systems - international	9.3	9.2	0.1	1.1%
Ophthalmology recurring revenues	16.2	16.2	0.0	0.0%
Ophthalmology OEM	0.5	0.7	(0.2)	(28.6)%
Continuing operations - ophthalmology revenues	\$ 33.2	\$ 32.3	\$ 0.9	2.8%

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Discontinued operations - aesthetics revenues	\$ 10.8	\$ 11.4	\$ (0.6)	(5.3)%
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### *Gross Profit.*

Gross profit increased \$0.1 million from \$16.2 million in 2010 to \$16.3 million in 2011. The increase in gross profits was driven by increased revenues offset by a reduction in gross margins from 50.1% to 49.1%. The reduction in gross margin was primarily attributable to a decrease in direct margins as a result of increased sales of lower margin systems.

### *Research and Development.*

Research and development expenses increased \$0.1 million or 2.6%, from \$3.8 million in 2010 to \$3.9 million in 2011. The increase is attributable to increases in headcount and therefore personnel costs incurred in engineering development projects as the Company continues to focus on new product introductions.

**Table of Contents***Sales and Marketing.*

Sales and marketing expenses increased \$0.4 million or 5.6%, from \$7.1 million in 2010 to \$7.5 million in 2011. The increase is primarily attributable to increased personnel costs associated with increased headcount and marketing programs.

*General and Administrative.*

General and administrative expenses increased \$0.1 million or 2.4%, from \$4.2 million in 2010 to \$4.3 million in 2011. Expenses were stable across the two periods.

*Legal Settlement, net of expenses.*

In November 2011, the Company entered into a license and distribution agreement with Alcon for the IRIDEX GreenTip SoftTip Cannula family of products. As part of the agreement Alcon agreed to pay \$1.5 million at signing as a settlement of past legal claims. The Company has treated this as part of its ongoing business and therefore as part of operating income because the agreement has established an ongoing commercial relationship that will benefit the Company's continuing business in subsequent periods.

*Legal Settlement and Interest and Other Expense, net.*

Income from the settlement with Synergetics of legal claims related to patent infringement amounted to \$0.8 million for both periods. The Company anticipates receiving an additional \$0.8 million in other income from the settlement, to be paid to the Company on April 16, 2012. The Company revalues the fair value of the contingent earn out liability it owes to RetinaLabs as a consequence of the asset purchase agreement the company entered into with RetinaLabs on a quarterly basis. As a result of entering into the license and distribution agreement with Alcon for the GreenTip Cannulas which the Company purchased from RetinaLabs, the Company determined that the fair value of the earn out had increased by \$0.3 million and the expense was recorded in the fourth quarter of 2011.

*Income Taxes.*

We recorded a provision for income taxes on continuing operations of \$0.3 million and an effective tax rate of 12% for fiscal year 2011 similar to a provision for income taxes of \$0.3 million and an effective tax rate of 16% for fiscal year 2010. Our tax rate is benefiting from a reduction in the valuation allowance we currently have booked against our deferred tax asset. Ultimately, assuming we remain profitable, the entire valuation reserve will be released and our tax rate will return to more normal levels. At the end of 2011 the valuation allowance totaled \$11.7 million.

**Comparison of 2010 and 2009***Revenues.*

Total revenues from continuing operations for 2010 were \$32.3 million compared with \$31.0 million in 2009, an increase of \$1.3 million or 4.2%. Our ophthalmology system revenues grew as a result in a resurgence in appreciation of the benefits of laser photocoagulation as a treatment modality amongst physicians and a recovery in capital spending worldwide. Competition for consumable products remains strong with increased price sensitivities amongst customers. Our OEM revenue is generated from a long standing relationship, the product is now in end of life and demand has and will continue to decline.

(in millions)	FY 2010	FY 2009	Change in \$	Change in %
Ophthalmology systems - domestic	\$ 6.2	\$ 5.2	\$ 1.0	19.2%
Ophthalmology systems - international	9.2	7.8	1.4	17.9%
Ophthalmology recurring revenues	16.2	16.6	(0.4)	2.4%
Ophthalmology OEM	0.7	1.4	(0.7)	(50.0)%
Continuing operations - ophthalmology revenues	\$ 32.3	\$ 31.0	\$ 1.3	4.2%
Discontinued operations - aesthetics revenues	\$ 11.4	\$ 12.2	\$ (0.8)	(6.6)%



*Gross Profit.*

Gross profit increased \$0.8 million from \$15.4 million in 2009 to \$16.2 million in 2010. The increase in gross profit was attributable to increased revenues and an improvement in gross margins from 49.8% to 50.1%.

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## **Table of Contents**

### *Research and Development.*

Research and development expenses increased \$0.5 million or 15.2%, from \$3.3 million in 2009 to \$3.8 million in 2010. The increase was primarily attributable to an increase in material costs consumed in engineering development projects and an increase in salary and employee benefits associated with a headcount increase.

### *Sales and Marketing.*

Sales and marketing expenses increased \$0.5 million or 7.6%, from \$6.6 million in 2009 to \$7.1 million in 2010. The increase was primarily attributable to increased commission expenses resulting from higher sales, and increased travel advertising and promotion costs directed at increasing sales.

### *General and Administrative.*

General and administrative expenses decreased \$0.1 million or 2.3%, from \$4.3 million in 2009 to \$4.2 million in 2010. Expenses were stable and comparable across the two periods.

### *Legal Settlement and Interest and Other Expense, net.*

Income from the settlement with Synergetics of legal claims related to patents infringement amounted to \$0.8 million for 2010 and 2009. The Company will receive a final payment of \$0.8 million on April 16, 2012. Interest and other expense, net consisting primarily of interest expense on bank debt, were \$0.1 million and \$0.2 million for 2010 and 2009, respectively.

### *Income Taxes.*

We recorded a provision for income taxes on the continuing operations of \$0.3 million and an effective tax rate of 16% for the fiscal year 2010 and a provision for income taxes of \$0.3 million and an effective tax rate of 15% for fiscal year 2009.

## **Liquidity and Capital Resources**

### *Comparison of 2011 and 2010*

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. During 2011 net cash provided by continuing operating activities was \$2.3 million which was generated from net income from continuing operations of \$2.1 million with non cash items added back of \$1.1 million less changes in working capital of \$0.9 million. This compares to net cash provided by continuing operating activities in 2010 of \$1.1 million which was generated from \$1.7 million of net income from continuing operations with non cash items added back of \$0.8 million less changes in working capital of \$1.4 million.

As of December 31, 2011, we had cash and cash equivalents of \$10.8 million, no debt outstanding and working capital of \$20.6 million compared with cash and cash equivalents of \$8.3 million, no debt and working capital of \$17.2 million as of January 1, 2011.

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 2010 and 2009*

During 2010 net cash provided by operating activities was \$1.1 million which was generated from net income from continuing operations of \$1.7 million with non cash items added back of \$0.8 million less changes in working capital of \$1.4 million. This compares to net cash provided by continuing operating activities in 2009 of \$3.0 million which was generated from net income from continuing operations of \$1.7 million with non cash items added back of \$0.8 million and changes in working capital provided an additional \$0.6 million.

**Table of Contents****Contractual Payment Obligations**

Our contractual payment obligations that were fixed and determinable as of December 31, 2011 were as follows (in thousands):

	Payments Due by Period					2016 and thereafter
	Total	2012	2013	2014	2015	
Operating leases payments	\$ 2,429	\$ 733	\$ 763	\$ 804	\$ 129	\$ 0
Total contractual cash obligations	\$ 2,429	\$ 733	\$ 763	\$ 804	\$ 129	\$ 0

**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 presented and accounted for in accordance with 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 held for sale 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 the Revenue Recognition, Multiple-Element Arrangements Section of Subtopic 605-25 of the Accounting Standards Codification (ASC). When the Company has objective and reliable evidence of fair value of the undelivered elements, it defers revenue attributable to the post-sale obligations and recognizes such revenue when the obligation is fulfilled. Otherwise, the Company defers all revenue related to the transaction until all elements are delivered. Revenue relating to extended warranty contracts is recognized on a straight line basis over the period of the applicable warranty contract. We recognize repair service revenue upon completion of the work.

*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. 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

**Table of Contents**

management judgment and estimates must be made and used in connection with establishing the sales returns allowance in any accounting period. Material differences may result in the amount and timing of our revenue for any period if management made different judgments or utilized different estimates. Our provision for sales returns is recorded net of the associated costs.

Similarly management must make estimates regarding the uncollectability 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 balance sheet. 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.*

The Company accrues for estimated warranty costs upon shipment of products. Actual warranty costs incurred have not materially differed from those accrued. The Company's warranty policy is applicable to products which are considered defective in their performance or fail to meet the product specifications. Warranty costs are reflected in the statement of operations as cost of revenues.

*Income Taxes.*

We account for income taxes in accordance with ASC 740, Income Taxes, 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 2011 and 2010, we have recorded a full valuation allowance for our deferred tax assets based on our past losses and 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.

*Accounting for Uncertainty in Income Taxes.*

We account for uncertain tax positions in accordance with ASC 740, Income Taxes. ASC 740 seeks to reduce the diversity in practice associated with certain aspects of measurement and recognition in accounting for income taxes. ASC 740 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax provision that an entity takes or expects to take in a tax return. Additionally, ASC 740 provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosures, and transition. Under ASC 740, an entity may only recognize or continue to recognize tax positions that meet a more likely than not threshold. In accordance with our accounting policy, we recognize accrued interests and penalties related to unrecognized tax benefits as a component of income tax expense. The impact on adoption of ASC 740 is more fully described in Note 14.

*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 stock-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.

Stock-based compensation expense for fiscal 2009 included compensation expense for all stock-based compensation awards granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provision of ASC 718. Stock-based compensation expense for all stock-based compensation awards granted after January 1, 2006 is based on the grant-date fair value estimated in accordance with the provisions of ASC 718. 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 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.



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## **Table of Contents**

### **Recently Issued and Adopted Accounting Standards**

In September 2011, the Financial Accounting Standards Board ( FASB ) issued Accounting Standards Update ( ASU ) 2011-08, Intangibles-Goodwill and Other (Topic 350): Testing Goodwill for Impairment. This standard is intended to simplify how entities, test goodwill for impairment. ASU 2011-08 permits an entity to first assess 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 goodwill impairment test described in Topic 350, *Intangibles-Goodwill and Other*. The more-likely-than-not threshold is defined as having a likelihood of more than 50%. ASU 2011-08 is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. Early adoption is permitted, including for annual and interim goodwill impairment tests performed as of a date before September 15, 2011, if an entity's financial statements for the most recent annual or interim period have not yet been issued or, for nonpublic entities, have not yet been made available for issuance. The Company will adopt this standard in the first quarter of fiscal year 2012 and does not expect its adoption to have a material effect on its financial position, results of operations, or cash flows.

In June 2011, FASB issued ASU 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income. ASU 2011-05 allows an entity the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In both choices, an entity is required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. ASU 2011-05 eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. It does not, however, change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. In December 2011, the FASB issued ASU 2011-12, *Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05*, in order to redeliberate the portion of the earlier ASU relating to presentation of reclassifications from other comprehensive income. Both updates are required for us the first quarter of 2012, applied retrospectively. As ASU 2011-05 and ASU 2011-12 are only presentation standards, we do not expect adoption of this standard to have a material impact on our financial position, results of operations, or cash flows.

### **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-US 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 31, 2011 and January 1, 2011 and the consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the three fiscal years 2011, 2010 and 2009 together with the related notes and the report of our independent auditors, are on the following pages. Additional required financial information is described in Item 15.

**Table of Contents**

**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 as of December 31, 2011 and January 1, 2011, and the related consolidated statements of income and comprehensive income, stockholders' equity and cash flows for each of the years in the three year period ended December 31, 2011. Our audits are also included the financial statement schedule listed in Item 15(2). IRIDEX Corporation's management is responsible for these consolidated financial statements and financial statement schedule. Our responsibility is to express an opinion on these consolidated financial statements and financial statement schedule 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 31, 2011 and January 1, 2011, and the results of their operations and cash flows for each of the years in the three year period ended December 31, 2011 in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, the related financial statement schedule, as of and for the years ended December 31, 2011, January 1, 2011 and January 2, 2010, when considered in relation to the consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

Burr Pilger Mayer, Inc.

East Palo Alto, California

March 30, 2012



**Table of Contents****IRIDEX Corporation****CONSOLIDATED BALANCE SHEETS**

(in thousands, except share and per share data)

	FY 2011 December 31, 2011	FY 2010 January 1, 2011
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 10,789	\$ 8,347
Accounts receivable, net of allowance for doubtful accounts of \$162 in 2011 and \$187 in 2010	5,551	5,457
Inventories, net	6,659	5,632
Prepaid expenses and other current assets	464	389
Current assets held for sale	6,043	6,547
Total current assets	29,506	26,372
Property and equipment, net	325	336
Other intangible assets, net	745	821
Goodwill	533	473
Other long-term assets	199	206
Non-current assets held for sale	841	1,012
Total assets	\$ 32,149	\$ 29,220
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,580	\$ 1,514
Accrued compensation	1,180	1,389
Accrued expenses	1,920	1,438
Accrued warranty	556	607
Deferred revenue	1,014	1,002
Current liabilities held for sale	2,663	3,247
Total current liabilities	8,913	9,197
Long-term liabilities:		
Other long-term liabilities	810	596
Total liabilities	9,723	9,793
Commitments and contingencies (Note 11)		
Stockholders equity:		
Convertible preferred stock, \$.01 par value:		
Authorized: 2,000,000 shares;		
Issued and outstanding: 500,000 shares in 2011 and 2010	5	5
Common stock, \$.01 par value:		
Authorized: 30,000,000 shares;		
Issued and outstanding: 8,917,824 shares in 2011 and 8,986,418 shares in 2010	92	89
Additional paid-in capital	42,032	41,168
Accumulated other comprehensive loss	(35)	(205)
Treasury stock, at cost	(1,078)	(430)
Accumulated deficit	(18,590)	(21,200)

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Total stockholders' equity	22,426	19,427
Total liabilities and stockholders' equity	\$ 32,149	\$ 29,220

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

**Table of Contents****IRIDEX Corporation****CONSOLIDATED STATEMENTS OF OPERATIONS**

(in thousands, except per share data)

	FY 2011 Year Ended December 31, 2011	FY 2010 Year Ended January 1, 2011	FY 2009 Year Ended January 2, 2010
Total revenues	\$ 33,159	\$ 32,308	\$ 31,032
Cost of revenues	16,869	16,106	15,593
Gross profit	16,290	16,202	15,439
Operating expenses:			
Research and development	3,913	3,753	3,315
Sales and marketing	7,458	7,095	6,556
General and administrative	4,259	4,163	4,339
Legal settlement, net of expenses	(1,274)	0	0
Total operating expenses	14,356	15,011	14,210
Income from continuing operations	1,934	1,191	1,229
Other income (expenses):			
Legal settlement	800	800	800
Interest and other expense, net	(296)	(30)	(225)
Total other income, net	504	770	575
Income from continuing operations before income taxes	2,438	1,961	1,804
Provision for income taxes	297	308	262
Income from continuing operations, net of tax	2,141	1,653	1,542
Income from discontinued operations, net of tax	469	1,393	1,043
Net income	\$ 2,610	\$ 3,046	\$ 2,585
Net income per share:			
Basic -			
Continuing operations	\$ 0.24	\$ 0.18	\$ 0.17
Discontinued operations	0.05	0.16	0.12
Net income	\$ 0.29	\$ 0.34	\$ 0.29
Diluted -			
Continuing operations	\$ 0.21	\$ 0.16	\$ 0.16
Discontinued operations	0.05	0.14	0.10
Net income	\$ 0.26	\$ 0.30	\$ 0.26
Weighted average shares used in computing net income per common share - basic	8,958	8,943	8,840

Weighted average shares used in computing net income per common share - diluted 10,225 10,134 9,940

**IRIDEX Corporation**

**CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME**

(in thousands)

	FY 2011 Year Ended December 31, 2011	FY 2010 Year Ended January 1, 2011	FY 2009 Year Ended January 2, 2010
Net income	\$ 2,610	\$ 3,046	\$ 2,585
Foreign currency translation adjustments	0	7	(20)
Recognition of accumulated foreign currency translation loss	170	0	0
Comprehensive income	\$ 2,780	\$ 3,053	\$ 2,565

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

**Table of Contents****IRIDEX Corporation****CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY**

(in thousands, except share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Treasury Stock	Accumulated Other Comprehensive Income (Loss)		Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			Income	Deficit		
FY 2008: Balances, January 3, 2009	500,000	\$ 5	8,824,301	\$ 89	\$ 39,105	\$ (430)	\$ (192)	\$ (26,831)	\$ 11,746	
Issuance of common stock under stock option plan			4,059		5				5	
Employee stock-based compensation expense					360				360	
Tax effect of stock compensation expense					350				350	
Foreign currency translation adjustments							(20)		(20)	
Exercise of common stock warrants, \$0.01 per share			20,000							
Net Income								2,585	2,585	
FY 2009: Balances, January 2, 2010	500,000	\$ 5	8,848,360	\$ 89	\$ 39,820	\$ (430)	\$ (212)	\$ (24,246)	\$ 15,026	
Issuance of common stock under stock option plan			34,558		88				88	
Employee stock-based compensation expense					551				551	
Tax effect of stock compensation expense					1				1	
Foreign currency translation adjustments							7		7	
Issuance of common stock in connection with RetinaLabs acquisition			103,500		444				444	
Contingent consideration - shares of common stock in connection with RetinaLabs acquisition					264				264	
Net Income								3,046	3,046	
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)				0	
Stock re-purchase			(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	

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

**Table of Contents****IRIDEX Corporation****CONSOLIDATED STATEMENTS OF CASH FLOWS**

(in thousands)

	FY 2011 Year Ended December 31, 2011	FY 2010 Year Ended January 1, 2011	FY 2009 Year Ended January 2, 2010
<b>Operating activities:</b>			
Net income	\$ 2,610	\$ 3,046	\$ 2,585
Less income from discontinued operations	469	1,393	1,043
Income from continuing operations	2,141	1,653	1,542
<b>Adjustments to reconcile net income to net cash used in operating activities:</b>			
Depreciation and amortization	410	297	440
Change in fair value of earn-out liability	280	0	0
Stock compensation cost recognized	478	488	271
Tax effect of stock compensation expense	2	1	84
Provision for doubtful accounts	(12)	0	84
Provision for inventory reserves	(46)	3	(92)
<b>Changes in operating assets and liabilities, net of assets and liabilities acquired:</b>			
Accounts receivable	(82)	(30)	483
Inventories	(981)	(1,525)	165
Prepaid expenses and other current assets	(75)	(30)	(97)
Other long-term assets	7	104	(81)
Accounts payable	66	7	(383)
Accrued compensation	(209)	59	69
Accrued expenses	285	49	350
Accrued warranty	(51)	40	13
Deferred revenue	12	(47)	12
Deferred rent	26	67	149
<b>Net cash provided by operating activities</b>	<b>2,251</b>	<b>1,136</b>	<b>3,009</b>
<b>Investing activities:</b>			
Acquisition of property and equipment	(203)	(193)	(190)
Cash paid in business combination	(75)	(225)	0
<b>Net cash used in investing activities</b>	<b>(278)</b>	<b>(418)</b>	<b>(190)</b>
<b>Cash flows from financing activities:</b>			
Proceeds from stock option exercises	321	88	5
Repurchase of common stock	(648)	0	0
Proceeds from borrowings	0	3,938	28,346
Repayment of borrowings	0	(6,297)	(30,007)
<b>Net cash used in financing activities</b>	<b>(327)</b>	<b>(2,271)</b>	<b>(1,656)</b>
<b>Net cash provided by operating activities from discontinued operations</b>	<b>797</b>	<b>2,688</b>	<b>3,606</b>

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Net cash used in investing activities from discontinued operations	0	0	(42)
Net cash used in financing activities from discontinued operations	0	(1,161)	(819)
Effect of foreign exchange rate changes from discontinued operations	(1)	7	(20)
Net cash provided by discontinued operations	796	1,534	2,725
Net increase (decrease) in cash and cash equivalents	2,442	(19)	3,888
Cash and cash equivalents, beginning of year	8,347	8,366	4,478
Cash and cash equivalents, end of year	\$ 10,789	\$ 8,347	\$ 8,366

**Supplemental disclosure of cash flow information:**

Cash paid during the year for:

Income taxes	\$ 522	\$ 439	\$ 160
Interest paid	\$ 1	\$ 57	\$ 242

**Supplemental disclosure of non-cash activities:**

Share issued at acquisition	\$ 0	\$ 444	\$ 0
Contingent consideration - cash	\$ 105	\$ 380	\$ 0
Contingent consideration - shares	\$ 0	\$ 264	\$ 0

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



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**Table of Contents**

**IRIDEX Corporation**

**Notes to Consolidated Financial Statements**

**1. Business of the Company**

*Description of Business.*

IRIDEX Corporation 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 predominantly through a direct sales force and internationally through approximately 70 independent distributors in over 100 countries. In December 2011, we entered into an agreement to sell our aesthetics business to Cutera, Inc. and reclassified the aesthetics business segment as discontinued operations. The transaction closed February 3, 2012. See Note 17 - Subsequent Event.

**2. Summary of Significant Accounting Policies**

*Financial Statement Presentation.*

The consolidated financial statements include the accounts of IRIDEX Corporation 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 2011 ended on December 31, 2011, fiscal 2010 ended on January 1, 2011, and fiscal 2009 ended on January 2, 2010. Consequently, each fiscal year included 52 weeks of operations.

*Reclassifications.*

On December 30, 2011 we entered into an agreement to sell our aesthetics business to Cutera, Inc. In accordance with US 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. We closed the transaction on February 2, 2012.

*Use of Estimates.*

The preparation of consolidated financial statements 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 presented and accounted for in accordance with 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 held for sale for all periods presented under the requirements of ASC 360.

**Table of Contents**

A summary of the assets and liabilities held for sale as of December 31, 2011 and January 1, 2011 is provided as follows (in thousands):.

	FY 2011 Year Ended December 31 2011	FY 2010 Year Ended January 1, 2011
<b>Assets:</b>		
Cash	\$ 382	\$ 666
Accounts receivable, net	2,065	2,070
Inventory, net	3,480	3,580
Other current assets	116	231
Property, plant & equipment, net	24	24
Intangible assets, net	813	976
Other assets	4	12
<b>Total assets</b>	<b>\$ 6,884</b>	<b>\$ 7,559</b>
<b>Liabilities:</b>		
Accounts payable	\$ 387	\$ 467
Accrued liabilities	967	1,299
Accrued warranty	234	349
Deferred revenue	1,075	1,132
<b>Total liabilities</b>	<b>\$ 2,663</b>	<b>\$ 3,247</b>

*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 \$0.1 million and \$0.2 million as of December 31, 2011 and January 1, 2011, respectively.

Similarly management must make estimates regarding the uncollectability 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 balance sheet. As of December 31, 2011, we had accounts receivable totaling \$5.6 million, net of an allowance for doubtful accounts of \$0.2 million. As of January 1, 2011, we had accounts receivable totaling \$5.5 million, net of an allowance for doubtful accounts of \$0.2 million. 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)

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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. 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.

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## **Table of Contents**

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 \$1.2 million and \$1.1 million and the accumulated amortization was \$0.5 million and \$0.2 million as of December 31, 2011 and January 1, 2011, respectively. The amortization of demos and loaners is credited to cost of goods 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 provided on a straight line basis over the estimated useful lives of the assets, which is generally three years. Our net property and equipment was \$0.3 million in both 2011 and 2010. We invested \$0.2 million in property and equipment in both 2011 and 2010. Capital expenditures in fiscal 2011 have been primarily for software and computer equipment, manufacturing equipment and leasehold improvements. In fiscal 2010, capital expenditures have been primarily for software and computer equipment and manufacturing equipment.

### *Valuation of Goodwill and Intangible Assets.*

The purchase method of accounting for acquisitions requires estimates and assumptions to allocate the purchase price to the fair value of net tangible and intangible assets acquired with any excess value being recorded as goodwill. There are a number of generally accepted valuation methods used to estimate fair value of intangible assets, and we use primarily a discounted cash flow method, which requires significant management judgment to forecast the future operating results and to estimate the discount factors used in the analysis. The amounts allocated to, and the useful lives estimated for intangible assets affect future amortization.

Goodwill and intangible assets determined to have indefinite lives are not amortized, but are subject to an annual impairment test in accordance with ASC 350, Intangibles - Goodwill and Other. See Note 7 - Goodwill, in Notes to Consolidated Financial Statements. 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 Impairment or Disposal of Long-Lived Assets Section of ASC 360, Property, Plant and Equipment. See Note 8 - Intangible Assets, in Notes to Consolidated Financial Statements.

### *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. When the Company has objective and reliable evidence of fair value of the undelivered elements, it defers revenue attributable to the post-sale obligations and recognizes such revenue when the obligation is fulfilled. Otherwise, the Company defers all revenue related to the transaction until all elements are delivered. Revenue relating to service contracts is recognized on a straight line basis over the period of the applicable service contract. We recognize repair service revenue upon completion of the work.

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 retention rights to any of our distributors.

**Table of Contents***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.

*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 31, 2011 and January 1, 2011 is provided as follows (in thousands):

FY 2009: Balance, January 2, 2010	\$ 1,049
Additions to deferral	1,390
Revenue recognized	(1,437)
FY 2010: Balance, January 1, 2011	\$ 1,002
Additions to deferral	1,403
Revenue recognized	(1,391)
FY 2011: Balance, December 31, 2011	\$ 1,014

*Warranty.*

The Company accrues for estimated warranty costs upon shipment of products. Actual warranty costs incurred have not materially differed from the amounts accrued. The Company's 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 statement of operations as cost of revenues. A reconciliation of the changes in the Company's warranty liability for the years ended December 31, 2011 and January 1, 2011, is provided as follows (in thousands):

FY 2009: Balance, January 2, 2010	\$ 567
Accruals for product warranties	176
Cost of warranty claims	(136)
FY 2010: Balance, January 1, 2011	\$ 607
Accruals for product warranties	171
Cost of warranty claims	(222)
FY 2011: Balance, December 31, 2011	\$ 556

*Shipping and handling costs.*

Our shipping and handling costs billed to customers are included in revenues and the associated expense is recorded in cost of revenues for all periods presented. Shipping and handling costs amounted to \$0.3 million for each of the fiscal years 2011, 2010 and 2009, respectively.

*Research and Development.*

Research and development expenditures are charged to operations as incurred.

*Advertising.*

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Advertising and promotion costs are expensed as they are incurred; such costs were approximately \$0.3 million in 2011, \$0.3 million in 2010, and \$0.4 million in 2009 and are included in sales and marketing expenses in the accompanying consolidated statements of operations.

### *Income Taxes.*

We account for income taxes in accordance with ASC 740, Income Taxes, 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

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## **Table of Contents**

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 2011 and 2010, we have recorded a full valuation allowance for our deferred tax assets based on our past losses and 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.

### *Accounting for Uncertainty in Income Taxes.*

We account for uncertain tax positions in accordance with ASC 740, Income Taxes. ASC 740 seeks to reduce the diversity in practice associated with certain aspects of measurement and recognition in accounting for income taxes. ASC 740 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax provision that an entity takes or expects to take in a tax return. Additionally, ASC 740 provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosures, and transition. Under ASC 740, an entity may only recognize or continue to recognize tax positions that meet a more likely than not threshold. In accordance with our accounting policy, we recognize accrued interests and penalties related to unrecognized tax benefits as a component of income tax expense. The impact on adoption of ASC 740 is more fully described in Note 14.

### *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 stock-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.

Stock-based compensation expense for fiscal 2009 included compensation expense for all stock-based compensation awards granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provision of ASC 718. Stock-based compensation expense for all stock-based compensation awards granted after January 1, 2006 is based on the grant-date fair value estimated in accordance with the provisions of ASC 718. 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 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.

### *Concentration of Credit Risk and Other Risks and Uncertainties.*

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

The Company markets its products to distributors and end-users throughout the world. Sales to international distributors are generally made on open credit terms and letters of credit. Management performs ongoing credit evaluations of our customers and maintains an allowance for potential credit losses. Historically, the Company has not experienced any significant losses related to individual customers or a group of customers in any particular geographic area. For the years ended December 31, 2011, January 1, 2011, and January 2, 2010 no single customer accounted for greater than 10% of total sales. No single customer accounted for more than 10% of our net accounts receivable balance as of December 31, 2011 and January 1, 2011.

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

### *Reliance on Certain Suppliers.*

Certain components and services used by the Company to manufacture and develop its products are presently available from only one or a limited number of suppliers or vendors. The loss of any of these suppliers or vendors would potentially require a significant level of hardware and/or software development efforts to incorporate the products or services into the Company's products.





**Table of Contents***Net Income per Share.*

Net income per share is computed in accordance with ASC 260, Earnings per Share. Basic net income per share is based upon the weighted average number of common shares outstanding during the period. Diluted net income per share is based upon the weighted average number of common shares outstanding and dilutive common stock equivalents outstanding during the period. Common stock equivalents consist of incremental common shares issuable upon the exercise of stock options and the conversion of Series A Preferred Stock into common stock and are calculated under the treasury stock method. Common stock equivalent shares from unexercised stock options and the conversion of Series A Preferred Stock are excluded from the computation for periods in which the Company incurs a loss as their effect is anti-dilutive or if the exercise price of such options is greater than the average market price of the stock for the period. See Note 16 - Computation of Basic and Diluted Net Income Per Common Share, in Notes to Consolidated Financial Statements.

*Recently Issued and Adopted Accounting Standards*

In September 2011, the Financial Accounting Standards Board ( FASB ) issued Accounting Standards Update ( ASU ) 2011-08, Intangibles-Goodwill and Other (Topic 350): Testing Goodwill for Impairment. This standard is intended to simplify how entities, test goodwill for impairment. ASU 2011-08 permits an entity to first assess 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 goodwill impairment test described in Topic 350, *Intangibles-Goodwill and Other*. The more-likely-than-not threshold is defined as having a likelihood of more than 50%. ASU 2011-08 is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. Early adoption is permitted, including for annual and interim goodwill impairment tests performed as of a date before September 15, 2011, if an entity's financial statements for the most recent annual or interim period have not yet been issued or, for nonpublic entities, have not yet been made available for issuance. The Company will adopt this standard in the first quarter of fiscal year 2012 and does not expect its adoption to have a material effect on its financial position, results of operations, or cash flows.

In June 2011, FASB issued ASU 2011-05, Comprehensive Income (Topic 220): Presentation of Comprehensive Income. ASU 2011-05 allows an entity the option to present the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. In both choices, an entity is required to present each component of net income along with total net income, each component of other comprehensive income along with a total for other comprehensive income, and a total amount for comprehensive income. ASU 2011-05 eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity. It does not, however, change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income. In December 2011, the FASB issued ASU 2011-12, *Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Update No. 2011-05*, in order to redeliberate the portion of the earlier ASU relating to presentation of reclassifications from other comprehensive income. Both updates are required for us the first quarter of 2012, applied retrospectively. As ASU 2011-05 and ASU 2011-12 are only presentation standards, we do not expect adoption of this standard to have a material impact on our financial position, results of operations, or cash flows.

**3. Business Combination****Ocunetics, Inc:**

On September 15, 2011, the Company acquired certain assets of Ocunetics, Inc. The purchase price for the acquired assets consisted of \$75 thousand in cash consideration and an earn-out provision fair valued at \$105 thousand. The earn-out is tied to future revenues and could result in additional cash and share consideration being paid to Ocunetics, Inc. based on the future performance of the acquired products and intellectual property.

In accordance with ASC 805, Business Combinations, the acquisition has been accounted for as a business combination. Under the purchase method of accounting, the assets acquired from Ocunetics, Inc. at the date of acquisition are recorded in the consolidated financial statements at their respective fair values as of the acquisition date. The excess of the purchase price over the fair value of the acquired net assets has been recorded as goodwill in the amount of \$60 thousand. This goodwill is expected to be non-deductible for tax purposes. The purchase price includes the fair value of the cash earn-out which is recorded as a long-term liability. No value was attributed to the contingent equity-based consideration because management does believe the likelihood of achieving the necessary targets in the future is remote. Costs incurred associated with the acquisition were immaterial. The financial results of Ocunetics, Inc. prior to the acquisition were immaterial for purposes of pro forma financial disclosures. As of the end of the reporting period, there has been no revenues or earnings generated by the acquiree since the acquisition date.



**Table of Contents**

*Identifiable intangible assets.* Intangible assets included in the purchase price allocation consist of technology patents of \$120 thousand, assigned an economic useful life whereby the economic value of the asset is its ability to provide the Company relief from royalty and is being amortized as a percentage of revenues generated per units sold.

*Goodwill.* Approximately \$60 thousand has been allocated to goodwill. Goodwill represents the excess of the purchase price over the fair value of the underlying net tangible and intangible assets. In accordance with ASC 350-20, goodwill, is not amortized but instead is tested for impairment at least annually (more frequently if certain indicators are present). In the event that management determines that the value of goodwill has become impaired, an accounting charge for the amount of impairment is incurred in the fiscal quarter in which the determination is made. The Company believes the goodwill realized was the result of a number of factors, including expected revenue growth opportunities for future products and the opportunity to commercialize acquired intellectual property.

**RetinaLabs:**

On April 8, 2010, the Company acquired substantially all of the assets of RetinaLabs. Pursuant to the terms of the purchase agreement, the Company acquired RetinaLabs' existing product family together with certain additional intellectual property that the Company anticipates incorporating into future products. The purchase price for the acquired assets consisted of \$250 thousand in cash consideration and 115 thousand unregistered shares of the Company's common stock issued at closing, and an earn-out. The earn-out is tied to future revenues and could result in additional cash and share consideration being paid to RetinaLabs based on the future performance of the acquired products and intellectual property.

In accordance with ASC 805, Business Combinations, the acquisition has been accounted for as a business combination. Under the purchase method of accounting, the assets acquired from RetinaLabs at the date of acquisition are recorded in the consolidated financial statements at their respective fair values as of the acquisition date. The excess of the purchase price over the fair value of the acquired net assets has been recorded as goodwill in the amount of \$473 thousand. This goodwill is expected to be non-deductible for tax purposes. The purchase price includes the fair value of the cash earn-out which is recorded as a long-term liability and the fair value of the contingent consideration for additional shares which is recorded in equity.

We incurred \$76 thousand of direct costs associated with the acquisition that were expensed as a component of general and administrative expense in the second quarter of fiscal year 2010. The amounts of revenue and earnings of the acquiree since the acquisition date are included in the consolidated statement of operations for the reporting period and have been immaterial to the consolidated financial statements. The financial results of RetinaLabs prior to the acquisition are immaterial for purposes of pro forma financial disclosures.

The determination of estimated fair value of acquired assets and liabilities requires management to make significant estimates and assumptions. We determined the fair value by applying established valuation techniques, based on information that management believed to be relevant to this determination. The following table summarizes the purchase price allocation of the fair value of the assets acquired at the date of acquisition:

The purchase price was as follows (in thousands):

At time of acquisition:	
Cash, net of escrow	\$ 225
Shares issued, net of escrow	444
Earn-out:	
Net present value of additional cash including escrow	380
Net present value of additional shares including escrow	264
<b>Total purchase price</b>	<b>\$ 1,313</b>

**Table of Contents**

The cost of the acquisition was allocated as follows (in thousands):

Identifiable intangible assets:	
Patents	\$ 600
Customer-related	240
Goodwill	473
Total purchase price	\$ 1,313

Valuing certain components of the acquisition, including primarily identifiable intangible assets, goodwill, and the earn-out liability, required us to make estimates that may be adjusted in the future. As of December 31, 2011, the earn-out liability was remeasured and increased by \$280 thousand as a result of the Company's latest estimate of future performance. The additional expense was recorded as a charge to interest and other expense, net in the consolidated statement of operations.

*Identifiable intangible assets.* Intangible assets included in the purchase price allocation consist of: (a) technology patents of \$600 thousand, assigned an economic useful life whereby the economic value of the asset is its ability to provide the Company relief from royalty and is being amortized as a percentage of revenues generated per units sold, and (b) customer-related intangible assets of \$240 thousand, assigned an economic life of 15 years being amortized on the straight line method.

*Goodwill.* Approximately \$473 thousand has been allocated to goodwill. Goodwill represents the excess of the purchase price over the fair value of the underlying net tangible and intangible assets. In accordance with ASC 350-20, goodwill, is not amortized but instead is tested for impairment at least annually (more frequently if certain indicators are present). In the event that management determines that the value of goodwill has become impaired, an accounting charge for the amount of impairment is incurred in the fiscal quarter in which the determination is made. The Company believes the goodwill realized was the result of a number of factors, including expected revenue growth opportunities for existing products and the opportunity to commercialize acquired intellectual property.

**4. Fair Value Measurement**

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

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities.

Level 2: Directly or indirectly observable inputs as of the reporting date through correlation with market data, including quoted prices for similar assets and liabilities in active markets and quoted prices in markets that are not active. Level 2 also includes assets and liabilities that are valued using models or other pricing methodologies that do not require significant judgment since the input assumptions used in the models, such as interest rates and volatility factors, are corroborated by readily observable data from actively quoted markets for substantially the full term of the financial instrument.

Level 3: Unobservable inputs that are supported by little or no market activity and reflect the use of significant management judgment. These values are generally determined using pricing models for which the assumptions utilize management's estimates of market participant assumptions.

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



**Table of Contents**

The carrying amounts of the Company's financial assets and liabilities, including cash and cash equivalents, accounts receivable, and accounts payable at December 31, 2011 and January 1, 2011, approximate fair value because of the short maturity of these instruments.

As of December 31, 2011 and January 1, 2011, financial assets and liabilities measured and recognized at fair value on a recurring basis and classified under the appropriate level of the fair value hierarchy as described above was as follows (in thousands):

	FY 2011: December 31, 2011 Fair Value Measurements				FY 2010: January 1, 2011 Fair Value Measurements			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
<b>Assets:</b>								
Money market funds	\$ 10,133			\$ 10,133	\$ 8,158			\$ 8,158
<b>Liabilities:</b>								
Contingent consideration-cash			\$ 765	\$ 765			\$ 380	\$ 380

The Company's Level 1 financial assets are money market funds whose fair values are based on quoted market prices. The Company does not have any Level 2 financial assets or liabilities. The Company's Level 3 financial liabilities are related to the fair value of the contingent consideration (the earn-out to be paid in cash) in connection with the RetinaLabs and OcuNetics acquisition. At December 31, 2011, observable market information was not available to determine the fair value of the Company's contingent consideration. Therefore, the fair value is based on valuation models that relied on Level 3 inputs including those that are based on probability of outcomes, expected cash flow streams, market discount rates and overall capital market liquidity. The valuation of the earn-out liability related to the RetinaLabs and OcuNetics acquisition are subject to uncertainties that are difficult to predict.

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

Balance as of January 1, 2011	\$ 380
Addition of earn-out related to OcuNetics, Inc. acquisition	105
Change in fair value of contingent consideration	280
Balance as of December 31, 2011	\$ 765

The change in the contingent consideration during fiscal year 2011 was due to the acquisition of OcuNetics and an increase in the fair value of the remaining RetinaLabs contingent consideration as a result of improving expectations of future cash flows.

**5. Inventories**

The components of the Company's inventories are as follows (in thousands):

	FY 2011 December 31, 2011	FY 2010 January 1, 2011
Raw materials and work in process	\$ 2,694	\$ 2,941
Finished goods	3,965	2,691
<b>Total inventories, net</b>	<b>\$ 6,659</b>	<b>\$ 5,632</b>

**6. Property and Equipment**

The components of the Company's property and equipment are as follows (in thousands):

	FY 2011 December 31, 2011	FY 2010 January 1, 2011
Equipment	\$ 6,372	\$ 6,211
Leasehold improvements	2,278	2,236
Less: accumulated depreciation and amortization	(8,325)	(8,111)
Property and equipment, net	\$ 325	\$ 336

Depreciation expense related to property and equipment was \$0.2 million, \$0.3 million thousand, and \$0.4 million for the fiscal years 2011, 2010 and 2009, respectively.

**Table of Contents****7. Goodwill**

The carrying value of goodwill was \$0.5 million at December 31, 2011 and January 1, 2011. Change in goodwill for the year ended December 31, 2011 is presented in the following table (in thousands):

	FY 2011 December 31, 2011	FY 2010 January 1, 2011
Balance, beginning of period	\$ 473	\$ 0
Goodwill as a result of acquisition	60	473
Balance, end of period	\$ 533	\$ 473

The change in goodwill during fiscal year 2011 was due to the acquisition of Ocutetics, and the change in goodwill during fiscal year 2010 was due to the acquisition of RetinaLabs.

Goodwill is tested for impairment at least annually or whenever there is a change in circumstances that indicates the carrying value of these assets may be impaired. The determination of whether any potential impairment of goodwill exists is based upon a two-step impairment test performed in accordance with ASC 350, Intangibles – Goodwill and Other. There was no impairment of goodwill recognized during fiscal year 2011 and fiscal 2010.

**8. Intangible Assets**

The purchase method of accounting for acquisitions requires estimates and assumptions to allocate the purchase price to the fair value of net tangible and intangible assets acquired. The amounts allocated to, and the useful lives estimated for, intangible assets, affect future amortization. There are a number of generally accepted valuation methods used to estimate fair value of intangible assets, and we use primarily a discounted cash flow method, which requires significant management judgment to forecast the future operating results and to estimate the discount factors used in the analysis. An asset is considered impaired if its carrying amount exceeds the value of future 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.

Future changes in events or circumstances, such as an inability to achieve the cash flows determined above, may indicate that the recorded value of the intangible assets will not be recovered through future cash flows and the Company may be required to record an impairment charge for the intangible assets or further modify the period of expected lives for the intangible assets.

The components of the Company's purchased intangible assets as of December 31, 2011 are as follows (in thousands):

	Useful Lives	FY 2011 Annual Amortization	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Useful Lives Remaining
Customer Relations	15 Years	\$ 16	\$ 240	\$ 28	\$ 212	13.4 Years
Patents	Varies	180	720	187	533	Varies
		\$ 196	\$ 960	\$ 215	\$ 745	

The components of the Company's purchased intangible assets as of January 1, 2011 are as follows (in thousands):



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	Useful Lives	FY 2010 Annual Amortization	Gross Carrying Value	Accumulated Amortization	Net Carrying Value	Useful Lives Remaining
Customer Relations	15 Years	\$ 12	\$ 240	\$ 12	\$ 228	14.4 Years
Patents	Varies	7	600	7	593	Varies
		\$ 19	\$ 840	\$ 19	\$ 821	

Aggregate amortization expense for the fiscal years 2011 and 2010 were \$196 thousand, and \$19 thousand, respectively. There were no amortization expense in fiscal year 2009.

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

Fiscal Year:	
2012	\$ 295
2013	270
2014	16
2015	16
2016	16
Thereafter	132
Total	\$ 745

**Table of Contents****9. Accrued Expenses**

	FY 2011 December 31, 2011	FY 2010 January 1, 2011
The components of the Company's accrued expenses are as follows (in thousands):		
Income taxes payable	\$ 210	\$ 253
Sales and use tax payable	94	96
Distributor commission	274	288
Customer deposits	117	183
Royalties payable	126	25
Earn-out - short term	197	0
Other accrued expenses	902	593
<b>Total accrued expenses</b>	<b>\$ 1,920</b>	<b>\$ 1,438</b>

**10. Bank Borrowings**

The Company has a Loan and Security Agreement ( "Loan Agreement" ) with Silicon Valley Bank ( "Lender" ) providing for a \$5.0 million secured revolving loan facility, with availability in certain circumstances, subject to an accounts receivable borrowing base formula. As of December 31, 2011, no funds have been requested or made available under the Loan Agreement.

Borrowings under the revolving loan facility accrue interest at a per annum rate equal to the Lender's prime rate as in effect from time to time plus a margin, subject to a minimum interest rate of 4.00%. Interest on borrowings under the revolving loan facility is payable monthly. The Company may borrow, repay and reborrow funds under the revolving loan facility until June 11, 2012, at which time the revolving loan facility matures and all outstanding amounts must be repaid. In certain circumstances, the Company may be required to immediately repay principal amounts outstanding when it receives payments on its accounts receivable. On June 11, 2011, the Company paid the annual non refundable commitment fee of \$12,500. In the event the Company elects to terminate the revolving loan facility before the maturity date, the Company is required to pay a fee in the amount of \$50,000.

All obligations under the Loan Agreement are secured by substantially all of the property of the Company, excluding the Company's intellectual property but including any proceeds derived from the Company's intellectual property.

The Loan Agreement contains covenants that include, among others, covenants that limit the Company's and its subsidiaries' ability to dispose of assets, enter into mergers or acquisitions, incur indebtedness, incur liens, pay dividends or make distributions on the Company's capital stock, make investments or loans, and enter into certain affiliate transactions, in each case subject to customary exceptions for a credit facility of this size and type. The Loan Agreement also contains a financial covenant requiring the Company to maintain a certain adjusted quick ratio. As of December 31, 2011, the Company was in compliance with all loan covenants.

**11. Commitments and Contingencies***Lease Agreements.*

The Company leases its operating facilities under a noncancelable operating lease. On December 22, 2009, the lease for the Mountain View, CA was amended and renewed to lease for an additional six year period beginning March 1, 2010 until February 28, 2015. The Company also leased office space in Lisses, France that was used for sales, service and support. In February 2012, this lease was assigned to Cutera, Inc. as part of the sale of our aesthetics business (see Note 17 - Subsequent Event). The lease is renewable annually and runs through 2018. The Company leased office space in Cwmbran, South Wales, which terminated in December 2009. Rent expense totaled \$0.6 million for each of the fiscal years 2011, 2010 and 2009.

Future minimum lease payments under current operating leases at December 31, 2011 are summarized as follows (in thousands):

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<b>Fiscal Year</b>	<b>Operating Lease Payments</b>
2012	\$ 733
2013	763
2014	804
2015	129
2016	0
Total future minimum lease payments	\$ 2,429

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## **Table of Contents**

### *License Agreements.*

The Company is obligated to pay royalties equivalent to 5% of sales on certain products under certain license agreements. Royalty expense was approximately \$0.2 million \$0.1 million and \$0.1 million for the fiscal years 2011, 2010 and 2009, respectively.

### *Indemnification Arrangements.*

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

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

In general, management believes that claims which are pending or known to be threatened, will not have a material adverse effect on the Company's financial position or results of operations and are adequately covered by the Company's liability insurance. However, it is possible that cash flows or results of operations could be materially affected in any particular period by the unfavorable resolution of one of more of these contingencies or because of the diversion of management's attention and the incurrence of significant expenses.

## **12. Stockholders' Equity**

### **Convertible Preferred Stock**

The Company is authorized to issue up to 2,000,000 shares of undesignated preferred stock from time to time in one or more series. During August 2007, the Company filed a Certificate of Designation authorizing the Company to issue up to 500,000 of the 2,000,000 shares of authorized undesignated preferred stock as shares of Series A Preferred Stock, par value \$0.01 per share.

In August 2007, the Company issued 500,000 shares of Series A Preferred Stock, convertible into 1 million shares of Common Stock, and warrants to purchase an aggregate of 600,000 shares of Common Stock at an exercise price of \$0.01 per share. The warrants were to expire December 31, 2007 but were exercised prior to that date. The purchase price for a unit of 1 share of Series A Preferred Stock and a warrant to purchase 1.2 shares of Common Stock was \$10.00, resulting in net proceeds to the Company of approximately \$4.9 million. Of the total \$4.9 million proceeds received, approximately \$2.3 million has been allocated to the common stock warrants based on their estimated fair value at the time of issuance.

In the event that the Common Stock of the Company trades on a trading market at or above a closing price equal to \$5.00 per share (as adjusted for capital reorganizations, stock splits, reclassifications, etc.) for a period of 30 consecutive trading days, the shares of Series A Preferred Stock shall automatically convert to common stock.

Holders of Series A preferred stock have preferential rights to noncumulative dividends when and if declared by the Board of Directors. In the event of liquidation, the holders have preferential rights to liquidation payments in the amount of the original purchase price plus declared and unpaid dividends, if any. At December 31, 2011, the aggregate liquidation preference was \$5,000,000.

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## **Table of Contents**

In addition, holders of Series A preferred stock have certain registration rights including the requirement that the Company file a Form S-3 registration statement within 90 days of becoming eligible to file a Form S-3 registration statement and the right to request that the Company file a Form S-1 registration statement any time after February 29, 2008.

If the holders notify the Company of their decision to have a registration statement filed, the Company has 90 days to cause the registration statement to be declared effective. If the registration statement is not filed within 90 days, the Company is obligated to pay the holders partial liquidated damages until the registration statement is declared effective. The Company shall pay to each holder an amount in cash equal to 1% of the aggregate purchase price paid for the original units of Series A Preferred Stock and warrants to purchase common stock. The maximum aggregate damages payable to the holders is 12% of the aggregate purchase price paid by the holders. If the Company fails to pay any partial liquidated damages in full within seven days of the date payable, the Company will pay interest thereon at a rate of 18% per annum (or the lesser maximum amount that is permitted to be paid by applicable law) to the holders.

The maximum potential amount of damages that the Company may have to pay the holders is \$600,000. The Company regards the probability of having to make this payment to the holders as remote and has therefore not recorded a liability to represent this potential obligation.

During 2009 the holders of the Series A preferred stock and the Company agreed to amend the Form S-3 registration rights. The agreement changed the clause requiring the Company to file a Form S-3 registration statement within 90 days of becoming eligible to a right to request the Company file a Form S-3 registration statement any time after June 30, 2009. In consideration for extending the period during which the Company is not required to file a registration statement, the Company issued the holders of Series A preferred stock warrants to purchase an aggregate of 20,000 shares Common Stock at an exercise price of \$0.01 per share. The warrants were exercised in fiscal year 2009. As of December 31, 2011, the Company has not received a request to file a Form S-3.

## **Stock-Based Compensation**

### *1998 Stock Plan.*

The 1998 Stock Plan (the 1998 Plan), as amended, provides for the granting to employees (including officers and employee directors) of incentive stock options and for the granting to employees (including officers and employee directors) and consultants of nonstatutory stock options, stock purchase rights (SPRs), restricted stock, restricted stock units, performance shares, performance units and stock appreciation rights. The exercise price of incentive stock options and stock appreciation rights granted under the 1998 Plan must be at least equal to the fair market value of the shares at the time of grant. With respect to any recipient who owns stock possessing more than 10% of the voting power of our outstanding capital stock, the exercise price of any option or SPR granted must be at least equal to 110% of the fair market value at the time of grant. Options granted under the 1998 Plan are exercisable at such times and under such conditions as determined by the Administrator; generally over a four year period. The maximum term of incentive stock options granted to any recipient must not exceed ten years; provided, however, that the maximum term of an incentive stock option granted to any recipient possessing more than 10% of the voting power of the Company's outstanding capital stock must not exceed five years. In the case of SPRs, unless the Administrator determines otherwise, the Company has a repurchase option exercisable upon the voluntary or involuntary termination of the purchaser's employment with the Company for any reason (including death or disability). Such repurchase option lapses at a rate determined by the Administrator. The purchase price for shares repurchased by the Company is the original price paid by the purchaser. In June of 2006, this plan was amended to shorten the contractual life of all option grants made after June 2006 to a seven year term. As of December 31, 2011 and January 1, 2011, no shares were subject to repurchase. The form of consideration for exercising an option or stock purchase right, including the method of payment, is determined by the Administrator. The 1998 Plan expired in February 2008.

### *Stand-Alone Options.*

In February 2007, the Compensation Committee of the Company's Board of Directors approved the grant of 235,000 non-qualified stock options, outside of the Company's existing stock plans, to a total of 54 new employees, both domestic and international, hired in connection with the Company's acquisition of the assets of the aesthetics business of Laserscope. The options were granted as of February 28, 2007 at an exercise price of \$10.06 per share. As of December 31, 2011 there were 10,000 shares outstanding and exercisable under these options.

### *2008 Equity Incentive Plan*

On June 11, 2008, the shareholders approved the adoption of the 2008 Equity Incentive Plan, (the Incentive Plan). There are no material changes in the Incentive Plan from the 1998 Stock Plan. The maximum aggregate number of shares that may be awarded and



**Table of Contents**

sold under the Incentive Plan is 300,000 shares plus any shares subject to stock options or similar awards granted under the 1998 Stock Plan that expire or otherwise terminate without having been exercised in full and shares issued pursuant to awards granted under the 1998 Stock Plan that are forfeited to the Company on or after the date the 1998 Stock Plan expires.

*Exchange Program*

In August 2009, we completed a one-time stock exchange program to exchange certain employee stock options issued under the 1998 Plan, the Incentive Plan or in connection with IRIDEX's acquisition of the assets of the aesthetics business of Laserscope for stock options issued under the Incentive Plan (the Exchange Program). The exchange offer was made to employees of the Company who, as the date of the exchange offer commenced, were actively employed. Members of our board of directors and our executive officers who are subject to the provisions of Section 16 of the Securities 1934 Exchange Act were not eligible to participate. The number of options held by eligible employees at the date of commencement was 663,018. Seventy two eligible employees surrendered 364,162 options in exchange for 197,116 new options. These new options were granted pursuant to the Exchange Program and have an exercise price of \$2.35 per share, the closing price of IRIDEX common stock as reported by Nasdaq on August 27, 2009.

The exchange of original options for new options was treated as a modification of the original options. As such, the Company will continue to recognize compensation cost for the incremental difference between the fair value of the new option and the fair value of the original options immediately before modification, reflecting the current facts and circumstances on the modification date, in addition to the compensation cost being incurred for the original options, over the vesting term of the new options. The Exchange resulted in an incremental expense of approximately \$38 thousand which is being recognized over the vesting periods of the new options which ranges from 6 months to 3 years.

The following table summarizes information regarding activity in our stock option plans during the fiscal years ended 2011, 2010 and 2009:

Information with respect to activity under these option plans are set forth below (in thousands except share and per share data):

	Outstanding Options			Weighted Average Exercise Price
	Shares Available for Grant	Number of Shares	Aggregate Price	
FY 2008: Balances, January 3, 2009	265,963	2,051,815	\$ 9,876	\$ 4.81
Additional shares reserved	872,735	0	0	0.00
Options granted	(280,416)	280,416	643	\$ 2.29
Options exercised	0	(4,059)	(6)	\$ 1.43
Options cancelled	744,664	(744,664)	(4,344)	\$ 5.79
Options expired	(740,789)	0	0	0
FY 2009: Balances, January 2, 2010	862,157	1,583,508	\$ 6,169	\$ 3.91
Additional shares reserved	93,299	0	0	0
Options granted	(195,800)	195,800	780	\$ 3.98
Options exercised	0	(34,558)	(88)	\$ 2.54
Options cancelled	126,684	(126,684)	(955)	\$ 7.54
Options expired	(126,203)	0	0	0
FY 2010: Balances, January 1, 2011	760,137	1,618,066	\$ 5,906	\$ 3.65
Additional shares reserved	63,063			
Options granted	(319,900)	319,900	1,148	3.59
Options exercised	0	(99,291)	321	3.24
Options cancelled	72,274	(72,274)	353	4.88
Options expired	(70,353)	0	0	0
FY 2011: Balances, December 31, 2011	505,221	1,766,401	\$ 7,728	\$ 3.61

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Restricted Stock Awards Granted

FY 2010: Balances, January 1, 2011	0	0	\$	0	\$	0
Stock awards granted	(100,315)	100,315		0		0
FY 2011: Balances, December 31, 2011	(100,315)	100,315	\$	0	\$	0

There were 2,271,622 shares reserved for future issuance under the stock option plans at December 31, 2011.



**Table of Contents**

The following table summarizes information with respect to stock options outstanding and exercisable at December 31, 2011:

Range of Exercise Prices	Options Outstanding			Options Vested and Exercisable		
	Number of Shares Outstanding at December 31, 2011	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number of Shares Exercisable at December 31, 2011	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)
\$0.82 - \$0.86	10,925	4.14	\$ 0.83	7,211	\$ 0.83	4.14
\$0.90 - \$0.90	182,532	3.76	\$ 0.90	133,949	\$ 0.90	3.95
\$0.99 - \$2.35	228,873	2.51	\$ 2.31	208,905	\$ 2.31	2.81
\$2.38 - \$2.78	229,449	2.88	\$ 2.56	217,891	\$ 2.56	3.17
\$2.88 - \$3.38	89,033	3.90	\$ 3.09	59,993	\$ 3.12	3.39
\$3.40 - \$3.40	210,555	5.29	\$ 3.40	72,240	\$ 3.40	3.15
\$3.41 - \$3.72	208,615	4.84	\$ 3.61	70,189	\$ 3.52	2.23
\$3.75 - \$4.43	224,473	4.97	\$ 4.19	121,326	\$ 4.18	4.75
\$4.47 - \$5.56	220,169	2.59	\$ 5.27	220,169	\$ 5.27	2.59
\$5.69 - \$10.06	161,777	2.24	\$ 7.70	161,777	\$ 7.70	2.32
<b>\$0.82 - \$10.06</b>	<b>1,766,401</b>	<b>3.67</b>	<b>\$ 3.61</b>	<b>1,273,650</b>	<b>\$ 3.74</b>	<b>2.90</b>

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

	Employee Stock Option Plan		
	FY 2011	FY 2010	FY 2009
Average risk free interest rate	0.98%	2.03%	1.76%
Expected life (in years)	4.70 years	4.75 years	3.35 years
Dividend yield	0	0	0
Average volatility	92.2%	88.2%	104.0%

The weighted average grant date fair value of option granted during 2011 as calculated using Black-Scholes was \$2.47 per share.

Option-pricing models require the input of various subjective assumptions, including the option's expected life and the price volatility of the underlying stock. The expected stock price volatility is based on analysis of the Company's stock price history over a period commensurate with the expected term of the options, trading volume of the Company's stock, look-back volatilities and Company specific events that affected volatility in a prior period. The Company had elected to use the simplified method for estimating the expected term prior to July 3, 2011. Effective July 3, 2011, the expected term of employee stock options represents the weighted average period the stock options are expected to remain outstanding and is based on the history of exercises and cancellations on all past option grants made by the Company, the contractual term, the vesting period and the expected remaining term of the outstanding options. The risk-free interest rate is based on the U.S. Treasury interest rates whose term is consistent with the expected life of the stock options. No dividend yield is included as the Company has not issued any dividends and does not anticipate issuing any dividends in the future.

The following table shows stock-based compensation expense included in Income from Continuing Operations in the Consolidated Statements of Operations for 2011, 2010 and 2009 (in thousands):

FY 2011 Year Ended December 31, 2011	FY 2010 Year Ended January 1, 2011	FY 2009 Year Ended January 2, 2010
--	--	--

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Cost of revenues	\$	60	\$	64	\$	75
Research and development		76		93		79
Sales and marketing		112		116		58
General and administrative		230		215		59
Total stock-based compensation expense-continuing operations	\$	478	\$	488	\$	271
Total stock-based compensation expense-discontinued operations		66		63		89
Total stock-based compensation expense	\$	544	\$	551	\$	360

**Table of Contents**

Approximately \$6 thousand, \$6 thousand and \$7 thousand of the stock based compensation expense recognized was capitalized into inventory as a component of overhead at December 31, 2011, January 1, 2011 and January 2, 2010, respectively.

Information regarding stock options outstanding, exercisable and expected to vest at December 31, 2011 is summarized below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (thousands)
Options outstanding	1,766,401	\$ 3.61	3.67	\$ 1,306
Options vested and expected to vest	1,656,746	\$ 3.64	3.56	\$ 1,231
Options exercisable	1,273,650	\$ 3.74	2.90	\$ 1,033

The aggregate intrinsic value in the table above represents the total pretax intrinsic value (the difference between the Company's closing stock price on the last trading day of fiscal 2011 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on December 31, 2011. This amount changes based on the fair market value of the Company's stock. The total intrinsic value of options exercised for fiscal years 2011, 2010 and 2009 were approximately \$84 thousand, \$46 thousand and \$5 thousand, respectively.

As of December 31, 2011, there were \$1.4 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements under both of the plans. The cost is expected to be recognized over a weighted average period of 2.92 years.

**Restricted Stock Awards/Restricted Stock Units**

Effective for the 2011 fiscal year, each non-employee member of the Board will receive an annual equity award of either restricted stock or a restricted stock unit (RSU), at the election of such Board member, in each case equal to \$20,000 worth of our common stock (determined at the fair market value of the shares at the time such award is granted) under the Company's 2008 Equity Incentive Plan. Each equity award or RSU vests in full on the one-year anniversary of the date of grant provided that the non-employee member continues to serve on the Board through such date.

**Summary of Restricted Stock Units and Awards**

The Company recognizes the estimated compensation expense of restricted stock units and awards, net of estimated forfeitures, over the vesting term. The estimated compensation expense is based on the fair value of the Company's common stock on the date of grant.

Information regarding the restricted stock units outstanding, vested and expected to vest as of December 31, 2011 is summarized below:

	Number of Shares	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value (thousands)
As of December 31, 2011			
Restricted stock units outstanding	90,189	1.84	\$ 337
Restricted stock units vested and expected to vest	73,283	1.70	\$ 274

The intrinsic value of the restricted stock units is calculated based on the closing price of IRIDEX shares as quoted on the Nasdaq Global Market on the last trading day of the year, December 30, 2011 of \$3.74.

For the year ended December 31, 2011, the Company granted 100,315 shares of restricted units to the Board of Directors with a weighted average grant date fair value of approximately \$355,000 or \$3.54 per share. There were no restricted stock units or awards granted in 2010.

Information regarding the restricted stock awards activity during the year ended December 31, 2011 is summarized below:

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	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at January 1, 2011	0	\$ 0.00
Restricted stock awards granted	10,126	\$ 3.95
Outstanding at December 31, 2011	10,126	\$ 3.95

**13. Employee Benefit Plan**

The Company has a plan known as the IRIS Medical Instruments 401(k) Trust to provide retirement benefits through the deferred salary deductions for substantially all US employees. Employees may contribute up to 15% of their annual compensation to the plan, limited to a maximum amount set by the Internal Revenue Service. The plan also provides for Company contributions at the discretion of the Board of Directors. Prior to the start of fiscal 2009, the Company suspended the matching contributions. Subsequent to the year end the Company reinstated a Company match in the amount of 50% of employee contributions up to a maximum of \$3 thousand per year.

**14. Income Taxes**

Pre-tax book income (loss) from continuing operations was comprised of the following:

	FY 2011 Year Ended December 31, 2011	FY 2010 Year Ended January 1, 2011	FY 2009 Year Ended January 2, 2010
United States	\$ 2,438	\$ 1,961	\$ 1,804
Foreign	0	0	0
<b>Total</b>	<b>\$ 2,438</b>	<b>\$ 1,961</b>	<b>\$ 1,804</b>

The provision for (benefit from) income taxes from continuing operations includes:

	FY 2011 Year Ended December 31, 2011	FY 2010 Year Ended January 1, 2011	FY 2009 Year Ended January 2, 2010
<b>Current:</b>			
Federal	\$ 267	\$ 288	\$ 256
State	30	20	6
Foreign	0	0	0
	297	308	262
<b>Deferred:</b>			
Federal	0	0	0
State	0	0	0
<b>Income tax provision</b>	<b>\$ 297</b>	<b>\$ 308</b>	<b>\$ 262</b>

**Table of Contents**

The Company's effective tax rate differs from the statutory federal income tax rate as shown in the following schedule:

	<b>FY 2011 Year Ended December 31, 2011</b>	<b>FY 2010 Year Ended January 1, 2011</b>	<b>FY 2009 Year Ended January 2, 2010</b>
Income tax provision at statutory rate	34%	34%	34%
State income taxes, net of federal benefit	(2%)	(1%)	3%
Permanent differences	0%	3%	11%
Research and development credits	(4%)	(4%)	(3%)
Change in valuation allowance	(16%)	(16%)	(30%)
Effective tax rate	12%	16%	15%

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

	<b>FY 2011 December 31, 2011</b>	<b>FY 2010 January 1, 2011</b>
Accruals and reserves	\$ 2,775	\$ 2,891
Deferred revenue	70	104
Fixed assets	488	587
Intangibles	6,959	7,304
Stock compensation	789	612
Net operating loss	120	120
Research and development credits	508	459
Other tax credits	1	37
Other	(10)	0
Net deferred tax asset	\$ 11,700	\$ 12,114
Valuation allowance	(11,700)	(12,114)
Net deferred tax assets	\$ 0	\$ 0

The Company has taxable income in 2011. While the Company has a recent history of income it is still in a position of a three year cumulative loss which is significant negative evidence against the realizability of its deferred tax assets. Management does not feel that it is more likely than not that the Company will be able to realize its deferred tax assets, and as such continues to record a full valuation allowance against deferred tax assets.

As of December 31, 2011, the Company had State net operating loss ( NOL ) carry forwards of \$3.3 million. Of the total state NOL s, \$1.3 million relates to windfall stock option deductions which, when realized, will be credited to equity. The state losses will begin to expire in 2012. The state of California has suspended the ability of companies to utilize their net operating losses for tax years 2010 and 2011.

As of December 31, 2011, the Company had Federal and State research credit carry forwards of approximately \$0.5 million and \$1.3 million, respectively, available to offset future tax liabilities. The Federal credits will begin expiring in 2026 if not used. The state research credits do not expire.

The above net operating losses and research and development credits are subject to IRC sections 382 and 383. In the event of a change in ownership as defined by these code sections, the usage of the above mentioned NOL s and credits may be limited.

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

**Table of Contents**

As of December 31, 2011, the Company had accrued \$67 thousand for payment of interest related to unrecognized tax benefits.

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

	FY 2011 Year Ended December 31, 2011	FY 2010 Year Ended January 1, 2011
Balance at the beginning of the year	\$ 865	\$ 637
Additions based upon tax positions related to the current year	58	67
Additions based upon tax positions related to the prior year	268	161
Balance at the end of the year	\$ 1,191	\$ 865

If the ending balance of \$1.2 million of unrecognized tax benefits at December 31, 2011 were recognized, \$0.3 million of the recognition would affect the income tax rate. The Company does not anticipate any material change in its unrecognized tax benefits of \$0.9 million over the next twelve months. The unrecognized tax benefits may change during the next year for items that arise in the ordinary course of business.

The Company files U.S. federal and state returns as well as foreign return in France. The tax years 2006 to 2011 remain open in several jurisdictions, none of which have individual significance.

**15. Major Customers and Business Segments**

The Company operates in one segment, ophthalmology. The Company develops, manufactures and markets medical devices. Our revenues arise from the sale of consoles, delivery devices, consumables, service and support activities.

For fiscal years 2011, 2010 and 2009 no customer individually accounted for more than 10% of our revenue.

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

	FY 2011 Year Ended December 31, 2011	FY 2010 Year Ended January 1, 2011	FY 2009 Year Ended January 2, 2010
United States	\$ 18,447	\$ 17,796	\$ 17,962
Europe	8,940	8,954	8,002
Rest of Americas	2,287	2,198	1,683
Asia/Pacific Rim	3,485	3,360	3,385
	\$ 33,159	\$ 32,308	\$ 31,032

Revenues are attributed to countries based on location of end customers. For fiscal years 2011, 2010 and 2009 no individual country accounted for more than 10% of the Company's sales, except for the United States, which accounted for 55.6%, 55.2%, and 57.9% of sales in 2011, 2010, and 2009 respectively.

**Table of Contents****16. Computation of Basic and Diluted Net Income Per Common Share**

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

	FY 2011 Year Ended December 31, 2011	FY 2010 Year Ended January 1, 2011	FY 2009 Year Ended January 2, 2010
<b>Numerator:</b>			
Income from continuing operations	\$ 2,141	\$ 1,653	\$ 1,682
Income from discontinued operations	469	1,393	903
Net income	\$ 2,610	\$ 3,046	\$ 2,585
<b>Denominator:</b>			
Weighted average shares of common stock (basic)	8,958	8,943	8,840
Effect of dilutive preferred shares	1,000	1,000	1,000
Effect of dilutive stock options	245	183	100
Effect of dilutive contingent shares	22	8	0
Weighted average shares of common stock (diluted)	10,225	10,134	9,940
<b>Per share data:</b>			
<b>Basic net income per share:</b>			
Net income before discontinued operations	\$ 0.24	\$ 0.18	\$ 0.19
Discontinued operations	0.05	0.16	0.10
Net income	\$ 0.29	\$ 0.34	\$ 0.29
<b>Diluted net income per share:</b>			
Net income before discontinued operations	\$ 0.21	\$ 0.16	\$ 0.17
Discontinued operations	0.05	0.14	0.09
Net income	\$ 0.26	\$ 0.30	\$ 0.26

The Company issued 500,000 shares of Series A Preferred Stock, convertible into 1 million shares of Common Stock in 2007. The effect of the conversion of the preferred shares into 1 million common shares is included in the computation of the diluted weighted average shares outstanding.

The Company excludes options from the computation of diluted weighted average shares outstanding if the exercise price of the options is greater than the average market price of the shares because the inclusion of these options would be anti-dilutive to earnings per share. Accordingly, at December 31, 2011 and January 1, 2011, respectively, stock options to purchase 713,462 and 809,997 shares were excluded from the computation of diluted weighted average shares outstanding.

On March 2, 2011, the Company purchased 75,698 shares of IRIDEX Common Stock from American Medical Systems Holdings, Inc. (AMS). These shares were the remaining holdings of IRIDEX Common Stock that were issued to AMS as part of the consideration for a 2007 transaction in which laser technologies and assets were purchased by IRIDEX from AMS.

**17. Subsequent Event**



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In February 2012, we sold our aesthetics business to Cutera, Inc. for approximately \$5.1 million. 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. The Company has evaluated subsequent events and has concluded that no additional subsequent events that require disclosure in the financial statements have occurred since the year ended December 31, 2011.

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

Not applicable.

### **Item 9A. Controls and Procedures**

*Evaluation of Disclosure Controls and Procedures.*

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

Based on management's evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2011, our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed,

## **Table of Contents**

summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

### *Management's Report on Internal Control over Financial Reporting.*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) of the Exchange Act. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2011 using the criteria for effective internal control over financial reporting as described in *Internal Control - Integrated Framework*, issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on their evaluation as of the end of the period covered by this Annual Report on Form 10-K, our Chief Executive Officer and Chief Financial Officer have concluded that our internal control over financial reporting was effective as of December 31, 2011.

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

### *Changes in Internal Control over Financial Reporting.*

There were no changes in our internal control over financial reporting that occurred during the fourth quarter of fiscal year 2011 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **Item 9B. Other Information**

Not applicable.

**Table of Contents**

**PART III**

Certain information required by Part III has been omitted from this Form 10-K. This information is instead incorporated herein by reference to our definitive Proxy Statement for our 2012 Annual Meeting of Stockholders (the Proxy Statement), which we will file within 120 days after the end of our fiscal year pursuant to Regulation 14A in time for our Annual Meeting of Stockholders to be held June 13, 2012.

**Item 10. Directors and Executive Officers and Corporate Governance**

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

**Item 11. Executive Compensation**

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

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

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

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

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

**Item 14. Principal Accountant Fees and Services.**

The information required by this item is incorporated herein by reference to Proposal Two - Ratification of Appointment of Independent Accountants in our Proxy Statement.

**Table of Contents****PART IV****Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K**

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

	<b>Page in Form 10-K Report</b>
<b>1. Financial Statements</b>	
<u>Report of Independent Registered Public Accounting Firm</u>	32
<u>Consolidated Balance Sheets as of December 31, 2011 and January 1, 2011</u>	33
<u>Consolidated Statements of Operations for the years ended December 31, 2011, January 1, 2011 and January 2, 2010</u>	34
<u>Consolidated Statements of Comprehensive Income (Loss) for the years ended December 31, 2011, January 1, 2011 and January 2, 2010</u>	34
<u>Consolidated Statements of Stockholders' Equity for the years ended December 31, 2011, January 1, 2011 and January 2, 2010</u>	35
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2011, January 1, 2011 and January 2, 2010</u>	36
<u>Notes to Consolidated Financial Statements</u>	37

**2. Financial Statement Schedule**

The following financial statement schedule of IRIDEX Corporation for the years ended December 31, 2011, January 1, 2011 and January 2, 2010 is filed as part of this Annual Report and should be read in conjunction with the Consolidated Financial Statements of IRIDEX Corporation

<u>Schedule II - Valuation and Qualifying Accounts</u>	61
Other schedules have been omitted because they are either not required, not applicable, or the required information is included in the consolidated financial statements or notes thereto.	

**3. Exhibits****Exhibit Index**

<b>Exhibits</b>	<b>Exhibit Title</b>
2.1(17)	Asset Purchase Agreement by and among Cutera, Inc., Registrant, and U.S. Bank, National Association, as Escrow Agent, dated December 30, 2011.
3.1(1)	Amended and Restated Certificate of Incorporation of Registrant.
3.2(2)	Amended and Restated Bylaws of Registrant.
4.1(3)	Certificate of Designation, Preferences and Rights of Series A Preferred Stock.
4.2(3)	Investor Rights Agreement, dated as of August 31, 2007, by and among the Company, BlueLine Capital Partners, LP; BlueLine Capital Partners III, LP and BlueLine Capital Partners II, LP.
4.3(4)	Amendment No. 1 to Investor Rights Agreement, dated as of March 31, 2009.
10.1(1)	Form of Indemnification Agreement with directors and officers.
10.2(5)	

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Lease Agreement dated December 6, 1996 by and between Zappettini Investment Co. and the Registrant, as amended pursuant to Amendment No. 1 dated September 15, 2003 and Amendment No. 2 dated December 22, 2008.

- 10.3(6)\* 1995 Director Option Plan.
- 10.4(7)\* 1998 Stock Plan.
- 10.5(8)\* 2005 Employee Stock Purchase Plan.
- 10.6(7)\* 2008 Equity Incentive Plan.
- 10.7(9)\* Form of 2008 Equity Incentive Plan Option Agreement.
- 10.8(10)\* Form of Stand-alone stock option agreement.
- 10.9(5)\* Change of Control Severance Agreement by and between the Company and James Mackaness, dated January 22, 2008.
- 10.10(11) Settlement Agreement, dated April 6, 2007, by and among Synergetics, Inc., Synergetics USA, Inc. and IRIDEX Corporation.
- 10.11(3) Securities Purchase Agreement, dated August 31, 2007, by and among BlueLine Capital Partners, LP, BlueLine Capital Partners III, LP, BlueLine Capital Partners II, LP and IRIDEX Corporation.

**Table of Contents**

10.12(12)	Loan and Security Agreement, dated as of June 11, 2010, between Silicon Valley Bank and the Company.
10.13(4)	Common Stock Purchase Warrant, dated March 31, 2009, issued to BlueLine Capital Partners, LP.
10.14(4)	Common Stock Purchase Warrant, dated March 31, 2009, issued to BlueLine Capital Partners II, LP.
10.15(4)	Common Stock Purchase Warrant, dated March 31, 2009, issued to BlueLine Capital Partners II, LP.
10.16(13)*	2011 Bonus Plan Summary.
10.17(14)*	2012 Bonus Plan Summary.
10.18(15)*	Employment Agreement by and between Registrant and Dominik Beck, dated as of August 16, 2011.
10.19(15)*	Executive Transition Agreement by and between Registrant and Theodore A. Boutacoff, dated October 10, 2011.
10.20(16)*	Form of 2008 Equity Incentive Plan Restricted Stock Award Agreement.
10.21(16)*	Form of 2008 Equity Incentive Plan Restricted Stock Unit Award Agreement.
21.1(1)	Subsidiaries of Registrant.
23.1	Consent of Burr Pilger Mayer Inc., Independent Registered Public Accounting Firm.
24.1	Power of Attorney (See page 62).
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document.
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101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

\* Indicates a management contract or compensatory plan or arrangement.

- (1) Incorporated by reference to the Exhibits filed with the Registration Statement on Form SB-2 (No. 333-00320-LA) which was declared effective on February 15, 1996.
- (2) Incorporated by reference to the Exhibits filed with the Registrant's Report on Form 8-K on November 21, 2007.
- (3) Incorporated by reference to the Exhibits filed with the Registrant's Report on Form 8-K on September 7, 2007.
- (4) Incorporated by reference to the Exhibits filed with the Registrant's Report on Form 8-K on April 6, 2009.
- (5) Incorporated by reference to the Exhibits filed with the Registrant's Report on Form 10-K for the year ended January 3, 2009.
- (6) Incorporated by reference to Exhibit 10.3 filed with the Registrant's Registration Statement on Form S-8 on August 3, 2004.
- (7) Incorporated by reference to the definitive proxy statement on Schedule 14A filed on May 4, 2009.
- (8) Incorporated by reference to the appendix filed with the Registrant's Proxy Statement for the Company's 2004 Annual Meeting of Stockholders which was filed on April 30, 2004.
- (9) Incorporated by reference to Exhibit 99.1 filed with Registrant's Registration Statement on Form S-8 on November 21, 2008.
- (10) Incorporated by reference to Exhibit 99.(d)(5) filed with the Registration Statement on Form SC TO-I July 30, 2009.
- (11) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Report on Form 10-Q for the quarter ended June 30, 2007.
- (12) Incorporated by reference to Exhibit 10.1 filed with the Registrant's Report on Form 8-K on June 16, 2010.

**Table of Contents**

- (13) Incorporated by reference to Exhibit 99.1 filed with the Registrant's Report on Form 8-K on March 10, 2011.
- (14) Incorporated by reference to Exhibit 99.1 filed with the Registrant's Report on Form 8-K on February 21, 2012.
- (15) Incorporated by reference to the Exhibits filed with the Registrant's Report on Form 8-K on October 12, 2011.
- (16) Incorporated by reference to the Exhibits filed with the Registrant's Report on Form 10-Q for the quarter ended July 2, 2011.
- (17) Incorporated by reference to the Exhibit 2.1 filed with the Registrant's Report on Form 8-K on January 4, 2012.

**Trademark Acknowledgments**

IRIDEX, the IRIDEX logo, IRIS Medical, OcuLight, SmartKey, EndoProbe, Apex, Aura, Lyra, Gemini, Venus, Coolspot and Dermastat are our registered trademarks. G-Probe, DioPexy, DioVet, TruFocus, TrueCW, DioLite, IQ 810, IQ 577, MicroPulse, OtoProbe, ScanLite, Symphony, VariLite, EasyFit, Endoview, MoistAir and GreenTip product names are our trademarks. All other trademarks or trade names appearing in this Annual Report on Form 10-K are the property of their respective owners.

**Table of Contents***Schedule II***IRIDEX CORPORATION AND SUBSIDIARIES****VALUATION AND QUALIFYING ACCOUNTS***(in thousands)*

<b>Description</b>	<b>Balance at Beginning of The Period</b>	<b>Additions</b>	<b>Deductions</b>	<b>Balance at End of The Period</b>
FY 2009: Balance for the year ended January 2, 2010:				
Allowance for doubtful accounts receivable	\$ 49	\$ 174	\$ 0	\$ 223
Provision for inventory	\$ 1,635	\$ 322	\$ (550)	\$ 1,407
FY 2010: Balance for the year ended January 1, 2011:				
Allowance for doubtful accounts receivable	\$ 223	\$ 0	\$ (36)	\$ 187
Provision for inventory	\$ 1,407	\$ 143	\$ (337)	\$ 1,213
FY 2011: Balance for the year ended December 31, 2011:				
Allowance for doubtful accounts receivable	\$ 187	\$ 14	\$ (39)	\$ 162
Provision for inventory	\$ 1,213	\$ 217	\$ 0	\$ 1,430



**Table of Contents****SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Mountain View, State of California, on the 30th day of March 2012.

**IRIDEX CORPORATION**

By: */s/ DR. DOMINIK BECK*  
**Dr. Dominik Beck**  
*President and Chief Executive Officer*

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

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

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<i>/s/ DR. DOMINIK BECK</i> <b>(Dr. Dominik Beck)</b>	<i>President, and Chief Executive Officer (Principal Executive Officer)</i>	March 30, 2012
<i>/s/ JAMES H. MACKANESS</i> <b>(James H. Mackaness)</b>	<i>Chief Financial Officer (Principal Financial and Accounting Officer)</i>	March 30, 2012
<i>/s/ SANFORD FITCH</i> <b>(Sanford Fitch)</b>	<i>Director</i>	March 30, 2012
<i>/s/ GARRETT A. GARRETTSON</i> <b>(Garrett A. Garrettson)</b>	<i>Director</i>	March 30, 2012
<i>/s/ JAMES B. HAWKINS</i> <b>(James B. Hawkins)</b>	<i>Director</i>	March 30, 2012
<i>/s/ WILLIAM M. MOORE</i> <b>(William M. Moore)</b>	<i>Chairman of the Board</i>	March 30, 2012
<i>/s/ RUÉDIGER NAUMANN-ÉTIENNE</i> <b>(Ruédiger Naumann-Etienne)</b>	<i>Director</i>	March 30, 2012



**Table of Contents**

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