IRIDEX CORP
Form 10-K
March 31, 2010
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington D.C. 20549

FORM 10-K

þ Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
for the fiscal year ended January 2, 2010

or

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

Commission file number 0-27598

IRIDEX CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**77-0210467**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

1212 Terra Bella Avenue, Mountain View CA 94043-1824

(Address of principal executive offices) (Zip Code)

(650) 940-4700

(Registrant s telephone number, including area code)

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

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

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

Common Stock, par value $0.01 per share

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

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

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

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

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

The aggregate market value of the voting common equity held by non-affiliates of the Registrant was approximately $8,684,467, as of July 2, 2009 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 17, 2010, Registrant had 8,850,235 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain parts of the Proxy Statement for the Registrant s 2010 Annual Meeting of Stockholders (the Proxy Statement) are incorporated by reference into Part III of this Annual Report on Form 10-K.

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PART I

This Annual Report on Form 10-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, such as statements relating to levels of future sales and operating results; gross margins; managing cash flows; general economic conditions and levels of international sales, and our current and future liquidity and capital requirements; market acceptance of our products; expectations for and sources of future revenues; leveraging our core business and increasing recurring revenues; broadening our product lines through product innovation and new treatments; our marketing programs and trends in healthcare; our ability to take advantage of economies-of-scale in product development and manufacturing; efforts to decrease costs; estimates regarding the size of our markets; 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 and delivery devices used to treat eye diseases in ophthalmology and skin conditions in dermatology (also referred to as aesthetics). Our products are sold in the United States predominantly through a direct sales force and internationally through approximately 100 independent distributors into 107 countries. Total revenues in 2009, 2008 and 2007 were $43.2 million, $48.5 million and $55.5 million, respectively. In 2009, we generated net income of $2.6 million, whereas we incurred net losses of $7.4 million and $22.3 million in 2008 and 2007, respectively. The net losses for 2008 and 2007 included impairment charges for the write down of Goodwill and Intangible assets of $5.4 million and $14.7 million, respectively.

Our ophthalmology products consist of laser systems, delivery devices and 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 (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 the light to the back of the eye. Therefore our ophthalmology business includes (i) a recurring revenue component, which consists of the sales of the consumable, single use EndoProbe devices, 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 the OcuLight product family which includes the OcuLight TX, the OcuLight Symphony (Laser Delivery System), OcuLight SL, OcuLight SLx, OcuLight GL, and OcuLight GLx laser photocoagulation systems, and the IQ 810 and IQ 577 laser systems. Our ophthalmology products contributed $31.0 million, $32.4 million and $32.3 million to our total revenues in 2009, 2008 and 2007, respectively.

Our aesthetics products consist of laser systems and handpieces that focus on the treatment of pigmented and vascular lesions, skin rejuvenation, skin tightening, hair reduction, leg veins, and acne. The aesthetics products include the VariLite, DioLite XP, Gemini, Aura-*i,* Lyra-*I,* and Venus-*i* Laser Systems. Our aesthetics products are primarily used in a dermatologist s or plastic surgeon s office and contributed $12.2 million, $16.1 million and $23.2 million to our total revenues in 2009, 2008 and 2007, respectively.

The IRIDEX ophthalmic and VariLite and DioLite XP laser systems consist of small, portable laser consoles and delivery devices. While dermatologists almost always use our laser systems in their offices or clinics, ophthalmologists and plastic surgeons 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, for both ophthalmology and dermatology, have been sold worldwide.

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IRIDEX Corporation was incorporated in California in February 1989 as IRIS Medical Instruments, Inc. In November 1995, we changed our name to IRIDEX Corporation and reincorporated in Delaware. Our executive offices are located at 1212 Terra Bella Avenue, Mountain View, California 94043-1824, and our telephone number is (650) 940-4700. We can also be reached at our website at www.IRIDEX.com, however, the information on, or that can be accessed through, our website is not part of this report. As used in this Annual Report on Form 10-K, the terms Company, IRIDEX, we, us and our refer to IRIDEX Corporation, a Delaware corporation, and when the context so requires, our wholly own subsidiaries, IRIS Medical Instruments, Inc. and Light Solutions Corporation, both California corporations, and IRIDEX UK, and IRIDEX France S.A.

The IRIDEX Strategy

We are one of the worldwide leaders in developing, manufacturing, marketing, selling and servicing innovative medical laser systems and associated instrumentation. At the beginning of 2008 we set out a three stage plan: (a) to return to positive cash flows; (b) drive for profitability; and (c) position ourselves for growth. In 2008 we made significant strides in paying off our obligations and in 2009 we were cash flow positive. In 2009 we became profitable. In 2010 we will focus on growth.

Key elements to our growth strategy are:

1. Leverage existing sales channels to drive more recurring revenues by adding additional consumable devices for our current ophthalmology market.

2. Introduce new complementary laser systems and durable delivery devices which either encourage replacement of the existing installed base, or expand the installed base by identifying new procedures or capabilities. We intend to continue our investment in research and development to improve the performance of our systems by developing innovative technologies which can address the customer needs.

3. These actions will consist of organic initiatives supplemented by acquisitions.

See Item 1A. Risk Factors Factors That May Affect Future Results *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.* and *Our Future Success Depends on Our Ability to Develop and Successfully Introduce New Products and New Applications*.

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 a 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 has list prices of between $150 and $200 to end customers.

Consoles

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

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. We believe that the smaller overall sizes, lower weights and low input power requirements to operate represent distinct advantages over competing products.

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Visible (Green) Photocoagulator Consoles. Our OcuLight TX, OcuLight GL and OcuLight GLx solid state and semiconductor-based photocoagulator consoles used in ophthalmology deliver visible (532nm) laser light. The OcuLight TX was first shipped in late 2006 and offers an optional remote control and wireless power-adjust footswitch. 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. In December 2002, we commenced shipment of the Millennium Endolase module, which is sold exclusively to Bausch & Lomb for use in their Millennium Microsurgical System. It integrates 532nm photocoagulator capability into Bausch & Lomb s array of microsurgical capabilities for the vitrectomy procedure. The Millennium Endolase module is compatible with the IRIDEX consumable EndoProbe handpieces and Laser Indirect Ophthalmoscope.

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.

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. It combines 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. We intend to add the IQ 577 in 2010.

Ophthalmic Delivery Devices

Our versatile family of consoles and delivery devices has been designed to accommodate the addition of new capabilities with a minimal incremental investment. 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. Doctors can install a slit lamp adapter in a few minutes and convert standard diagnostic slit lamps into a therapeutic photocoagulator delivery system. Slit lamp adapters are used in treatment procedures for both retinal diseases and glaucoma. These devices are available in a wide variety of spot diameters. Our standard slit lamp adapters have a single fiber and deliver laser light from a single laser console. Our Symphony slit lamp adapter 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 slit lamp adapters, 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 consumable disposable probes are available in tapered, angled, stepped, aspirating, illuminating, and adjustable styles.

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 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.

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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 or an ASC and are non-elective and covered by insurance.

	Procedure	Console	Delivery Devices
Age-related Macular Degeneration Diabetic Retinopathy Macular Edema	Retinal Photocoagulation	Infrared & Visible	Slit Lamp Adapter
	Grid Retinal Photocoagulation	Infrared & Visible	Slit Lamp Adapter & Operating Microscope Adapter,
	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*
Glaucoma			
Primary Open-Angle	Trabeculoplasty	Infrared & Visible	Slit Lamp Adapter
Angle-closure	Iridotomy	Infrared & Visible	Slit Lamp Adapter
Uncontrolled Glaucoma	Transscleral Cyclophotocoagulation	Infrared	G-Probe*
Retinal Tears and Detachments	Retinopexy Retinal Photocoagulation Vitrectomy Procedure	Infrared & Visible	Slit Lamp Adapter, Laser Indirect Ophthalmoscope, Operating Microscope Adapter, EndoProbe*
	Transscleral Retinal Photocoagulation	Infrared	DioPexy Probe
Retinopathy of Prematurity	Retinal Photocoagulation	Infrared	Laser Indirect Ophthalmoscope
Ocular Tumors	Retinal Photocoagulation	Infrared	Slit Lamp Adapter, Operating Microscope Adapter, Laser

Macular Holes	Vitrectomy Procedure	Visible	Indirect Ophthalmoscope EndoProbe*

* Consumable single use products

Aesthetics Products

Although light-based products are used in a variety of aesthetics applications, our aesthetics business focuses primarily on pigmented and vascular lesions, skin rejuvenation, skin tightening, hair reduction, leg veins, and acne, treatments that make up three-quarters of all aesthetics laser procedures.

Consoles

Our aesthetics laser consoles, which are described below, incorporate high powered solid state and semi-conductor technology.

Combination Infrared/Visible wavelength laser consoles: This includes the Gemini and VariLite.

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The Gemini combines the best features of the Lyra and Aura systems, resulting in one of the most comprehensive and versatile multi-use systems available. It is FDA-cleared for use in 21 different aesthetics applications. It is one of the few dual wavelength lasers on the market, offering 532 nm KTP and 1064 nm Nd:YAG laser wavelengths. The KTP is a fast, high power laser used for skin rejuvenation and treatment of acne, pigmented lesions and other shallow vascular lesions. The Nd:YAG allows for deeper penetration and is used for hair reduction, wrinkle reduction, and the treatment of leg veins and other lesions.

The VariLite is a unique product in the aesthetics business. It includes both 532 nm and 940 nm lasers, which are used for deeper and more recalcitrant vascular lesions that are not easily treated with 532 nm. The 940nm wavelength is also more effective on venous lakes than 532 nm lasers.

Visible (Green) Consoles. The DioLite XP and Aura-*i* deliver (532 nm) laser light. These lasers deliver from three watts to 20 watts of power that is used for 14 FDA cleared applications ranging from vascular and pigmented lesions to acne.

Infrared Consoles: This includes the Lyra-i and Venus-i Laser System.

The Lyra-i uses a 1064 nm wavelength. This wavelength penetrates deeply into the skin to reach the hair bulb, leg veins, and the papillary dermis. It is used to treat 11 FDA cleared applications.

The Venus-*i* Laser System is a portable, lightweight, high power Erbium:YAG laser system for skin resurfacing. It provides treatment for wrinkles and moderate sun damage, and can be used on both facial and non-facial skin. Its unique flat beam profile maintains consistent laser energy in the therapeutic range and avoids dangerous hot spots. It is roughly half the size and weight of most other Erbium systems currently available.

Aesthetics Delivery Devices

VersaStat-*i* and VersaStat 10 mm Handpieces. These handpieces are used on the Gemini, Aura-*i* and Lyra-*i* consoles. The VersaStat-*i* has an adjustable spot size that allows the physician to match the spot size to the treatment area. It is adjustable from 1 mm to 5 mm in 0.1 mm increments. The handpiece treats a wide range of conditions, including small telangictasias and large blue veins without the need to change handpieces. The VersaStat 10 mm Handpiece allows the physician the ability to treat larger areas, adding to speed and efficiency of treatments. Both handpieces offer contact cooling, which allows for increased patient comfort during treatments.

Dermastat Handpieces. These handpieces are used with the Gemini and Aura-*i.* They are used as tracing instruments for the treatment of small cutaneous surface lesions, typically vascular, such as telangiectasia.

DioLite Handpieces. These handpieces are handheld instruments used in the treatment of vascular and pigmented skin lesions. These devices are available in 200, 500, 700, and 1,000 micron spot diameters.

VariLite Handpiece. The VariLite Handpiece is a handheld instrument used in the treatment of vascular, pigmented cutaneous skin lesions and small area hair reduction. Ergonomic handpieces can be used with both the 532 nm and 940 nm wavelengths and are available in 700, 1,000, 1,400, 2,000 and 2,800 micron spot diameter.

ScanLite Scanner. The ScanLite XP is a computer pattern generator with integrated controls designed to enhance the capabilities of the DioLite XP and VariLite systems. They allow rapid and uniform treatment of larger-area vascular and pigmented skin lesions.

Aesthetics Treatments

The following chart lists the procedures for treating skin diseases that can be addressed by utilizing our dermatology laser systems. These procedures are normally performed in a physician s office and are elective and private pay.

Condition	Procedure	Console	Delivery Devices
Vascular Lesions	Selective Photothermolysis	Visible	DioLite Handpiece
Pigmented Lesions			Versastat-*i*

Cutaneous Lesions			Versastat 10 mm
Acne			Dermastat
Skin Rejuvenation			ScanLite
Hair Reduction			VariLite Handpiece
Leg Veins	Selective Photothermolysis	Infrared	Versastat-*i*
Hair Reduction			Versastat 10 mm
Wrinkle Reduction	Skin Resurfacing	Infrared	Articulated Arm
Scars			
Acne Scar Reduction			

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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 17 engineers, scientists and regulatory professionals with experience in various aspects of medical products, laser systems, delivery devices and clinical techniques with a focus to introduce 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 the necessary disciplines of the Company from product inception through customer acceptance. This process facilitates reliable new product innovations and a consistent pipeline of innovative products for our customers.

Our research activities are managed internally by our 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 treat diseases, to treat patients earlier in the treatment regimen and to reduce the side effects of treatment. We spent $3.6 million on research and development in 2009, $4.0 million in 2008 and $5.8 million in 2007.

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*

Customers and Customer Support

Our products are currently sold to ophthalmologists particularly those specializing in retina, glaucoma and pediatrics dermatologists and plastic surgeons. 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 2009, 2008 or 2007.

We are continuing our efforts to broaden our customer base through the development of new products and new applications of our existing products for use by ophthalmologists and dermatologists. We currently estimate that there are approximately 18,000 ophthalmologists in the United States and 55,000 internationally who are potential customers. Additionally, we estimate that there are approximately 5,000 and 18,000 hospitals in the United States and internationally, respectively, as well as approximately 5,000 ambulatory surgical centers in the United States which potentially represent multiple unit sales. We believe there are approximately 9,000 dermatologists and approximately 8,000 plastic surgeons in the United States who are potential customers. Because independent ophthalmologists and dermatologists frequently practice at their own offices, as well as through affiliations with hospitals or other medical centers, each independent ophthalmologist, dermatologist, plastic surgeon, office, hospital and medical center is a potential customer for our products.

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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 and small aesthetics products and we provide field service for the large aesthetics products we acquired in the Laserscope acquisition. 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. Our direct sales force is separated into two separate divisions, one for ophthalmology and one for aesthetics. In total we had a direct sales force of 15 employees who were engaged in sales efforts within the United States as of January 2, 2010. Our sales and marketing organization is based at our corporate headquarters in Mountain View, California with area sales managers located throughout the United States.

We sell and market our products internationally through approximately 100 independent distributors into over 107 countries. International sales represented 42.1%, 44.4% and 46.1% of our sales in 2009, 2008 and 2007, respectively. We believe that our international sales will continue to represent a significant portion of our revenues for the foreseeable future. As a result of the Laserscope acquisition we acquired two wholly owned subsidiaries, one located in the UK and the other in France. Our subsidiaries are responsible for selling, marketing and servicing our aesthetics products in their local geography. In June 2008, we transitioned the responsibility for the sales and service of our aesthetics products in the UK to an independent distributor. Our other international sales are made principally to customers in Europe, Asia, the Pacific Rim, the Middle East and Latin America. Our indirect international sales are administered through our corporate headquarters in Mountain View, California. 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*.

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 participate in over 100 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 and dermatology 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 infrared and visible light 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. As of January 2, 2010, we had a total of 51 employees engaged in manufacturing activities.

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, ear, nose and throat (ENT)/otolaryngology and dermatology.

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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 such third parties 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 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. 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.*

Competition

Competition in the market for laser systems and delivery devices used for ophthalmic and aesthetics treatment procedures is intense and is expected to increase. This market is also characterized by rapid 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.

Our principal competitors in ophthalmology are Alcon Inc., Carl Zeiss Meditec AG, Nidek Co. Ltd, Synergetics, Ellex Medical Lasers, Ltd. 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 such as Lucentis/Avastin (Genentech), and to a lesser extent Visudyne (Novartis) and Macugen (OSI Pharmaceuticals) compete rigorously with traditional laser procedures.

In aesthetics our principal competitors are Cutera, Syneron, Palomar Technologies, Inc., Sciton, Lumenis Ltd. and Cynosure.

Some ophthalmic and aesthetic 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. We file patent applications to protect technology, inventions and improvements that are significant to the development of our business. We have been issued sixteen United States patents and five foreign patents on the technologies related to our products and processes, which have expiration dates ranging from 2010 to 2023. We have approximately six pending patent applications in the United States and five foreign pending patent applications that have been filed. Our patent applications may not be approved.

Along with the acquisition of the AMS/Laserscope aesthetic products, we acquired a royalty-free license to eleven of the AMS/Laserscope patents. In addition, we acquired a license to a Palomar patent under which royalties are paid to Palomar based upon a percentage of sales of certain products acquired from AMS/Laserscope.

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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 to be 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 (the 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 your device is a pre-amendments device (on the market prior to the passage of the medical device amendments in 1976, or substantially equivalent to such a device) and PMAs have not been called for. In that case, a 510(k) will be the route to market. A 510(k) clearance will be granted if the submitted information establishes that the proposed device is substantially equivalent to a legally marketed Class I or II medical device, or to a Class III medical device for which the FDA has not called for a PMA. The FDA may determine that a proposed device is not substantially equivalent to a legally marketed device, or that additional information or data are needed before a substantial equivalence determination can be made. A request for additional data may require that clinical studies of the device s safety and efficacy be performed.

Commercial distribution of a device for which a 510(k) notification is required can begin only after the FDA issues an order finding the device to be substantially equivalent to a previously cleared device. The FDA has recently been requiring a more rigorous demonstration of substantial equivalence than in the past. Even in cases where the FDA grants a 510(k) clearance, it can take the FDA from three to 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) clearance 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 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 510(k) clearance or PMA approval is obtained. Also, in these circumstances, we may be subject to significant regulating fines or penalties.

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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 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 impacted 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 (CMS) reimburses hospitals on a prospectively-determined fixed amount for the costs associated with an in-patient hospitalization based on the patient s discharge diagnosis. CMS reimburses physicians a prospectively-determined fixed amount based on the procedure performed, regardless of the

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actual costs incurred by the hospital or physician in furnishing the care and regardless of the specific devices used in that procedure. Reimbursement issues have affected sales of our ophthalmic products to a greater extent than sales of our aesthetics products because aesthetics procedures, in general, are not covered under most insurance programs and the cost of these procedures are paid for by the patient.

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

At January 2, 2010 we had a total of 150 full-time employees (144 in the U.S. and 6 in France), including in the US: 81 in operations and service, 31 in sales and marketing, 17 in research and development and 15 in finance and administration. We also employ, from time to time, a number of temporary and part-time employees as well as consultants on a contract basis. At January 2, 2010, we employed 16 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.

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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*, as soon as reasonably practicable after such reports are electronically filed with the Securities and Exchange Commission, however, the information on, or that can be accessed through, our website is not part of this report. Additionally, these filings may be obtained by visiting the Public Reference Room of the SEC at 100 F Street, NE, Washington, DC 20549 or by calling the SEC at 1-800-SEC-0330, by sending an electronic message to the SEC at publicinfo@sec.gov or by sending a fax to the SEC at 1-202-777-1027. In addition, the SEC maintains a website (www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically.

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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 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 cause a slowdown in 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.

During the past several quarters, macro-economic issues involving the broader financial markets, including the housing and credit system and general liquidity issues in the securities markets, have negatively impacted the economy and have and may in the future negatively affect our growth. In addition, weak economic conditions and declines in consumer spending and consumption may harm our operating results. Purchases of our products are often discretionary. In the current economic climate, customers or potential customers may delay, reduce or forego their purchases of our products and services, which has impacted and could in the future impact, our business in a number of ways, including lower prices for our products and services and reduced or delayed sales. There could be a number of follow-on effects from the current financial crisis 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 increased expense or inability to obtain future financing.

If the negative macro-economic conditions persist, or if the economy enters a prolonged period of decelerating growth, our results of operations may be harmed.

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 and aesthetics markets. 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, dermatologists, plastic surgeons, 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, in which the availability of credit is limited and purchasers may delay capital investments or place additional emphasis on price when making their purchase decision;
- 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 from recurring revenues including consumable EndoProbe devices and service. Our ability to increase recurring revenues from the sale of consumable EndoProbe devices will depend primarily upon the features of our current products and product innovation, the quality of our products, ease of use and prices of our products, including the relationship to prices of competing delivery devices. The level of our service revenues will depend on the quality of service we

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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.

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 January 2, 2010, our international sales were $18.2 million or 42.1% of total sales. We anticipate that international sales will continue to account for a significant portion of our revenues, particularly ophthalmology, in the foreseeable future. None of our international revenues and costs has been denominated in foreign currencies, other than sales made by our French subsidiary. 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. The factors stated above could have a material adverse effect on our business, financial condition or results of operations. Our international operations and sales are subject to a number of other risks and potential costs, including:

- impact of recessions in global economies and availability of credit;