



**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

Washington D.C. 20549

**FORM 10-K**

**Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
for the fiscal year ended December 31, 2005**

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:  
None

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 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. See definition of "accelerated filer" and "large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer  Non-accelerated filer

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

The aggregate market value of the voting common equity held by non-affiliates of the Registrant was approximately \$ 28,736,448, as of July 2, 2005, 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 National Market System. 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 23, 2006, Registrant had 7,615,618 shares of common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Certain parts of the Proxy Statement for the Registrant's 2006 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; actual order rate and market acceptance of our products; opportunities in the adjunctive visualization systems market and our efforts to provide total disease management solutions; expectations for future sales growth, generally, including expectations of additional sales from our new products and new applications of our existing products; leveraging our core business and increasing recurring revenues; broadening our product lines through product innovation; our marketing programs, generally, including Valued IRIDEX Partner Program; the innovation potential for production cost decreases and higher gross estimate of 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; results of clinical studies and risks associated with bringing new products to market, general economic conditions and levels of international sales. 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 “Part I, Item 1, Business,” and “Part II, Item 7, Management’s Discussion and Analysis of Financial Condition and Results of Operations-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 77 independent distributors into 107 countries. Total product sales in 2005, 2004 and 2003 were \$37.0 million, \$32.8 million and \$31.7 million respectively, which generated a net income (loss) from continuing operations for those corresponding years of \$1,671,000, (\$402,000) and \$371,000.

Our ophthalmology products are used in the treatment of serious eye diseases, including the three leading causes of irreversible blindness, age-related macular degeneration (AMD), diabetic retinopathy and glaucoma. 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 requires a disposable single use laser probe (EndoProbe) to deliver the light to the back of the eye. The current family of OcuLight laser systems, which accounts for the majority of our revenues, is used for ophthalmic applications primarily in operating rooms, clinics and doctors’ offices includes the IRIS Medical IQ810 Laser System, the OcuLight Symphony (Laser Delivery System), OcuLight SL, OcuLight SLx, OcuLight GL and OcuLight GLx laser photocoagulation systems. Our ophthalmology products contributed \$30.7 million, \$27.8 million and \$26.2 million to our total revenues in 2005, 2004 and 2003, respectively.

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Our dermatology products treat skin conditions, primarily vascular and pigmented lesions and remove unwanted hair. Our dermatology laser systems include the DioLite XP, DioLite 532 and the VariLite Dual Wavelength Laser systems. In 2005, we discontinued selling the Apex hair removal laser system. Our dermatology products are primarily used in the practitioner's office and contributed \$6.4 million, \$5.1 million and \$5.5 million to our total revenues in 2005, 2004 and 2003, respectively.

Each ophthalmic and dermatology laser system consists of a small, portable laser console and delivery devices. While dermatologists almost always use our laser systems in their offices, ophthalmologists use our laser systems in hospital operating rooms (OR), ambulatory surgical centers (ASC) and their offices. In the OR and ASC, ophthalmologists use our laser with either an indirect laser ophthalmoscope (LIO) or a disposable, single use EndoProbe. Our business includes a recurring revenue component which includes the sales of the disposable, single use laser probes, EndoProbes, combined with the repair, servicing and extended warranty protection for our laser systems. Since our first shipment in 1990, more than 7,775 IRIDEX medical laser systems have been sold worldwide.

IRIDEX Corporation was incorporated in California in February 1989 as IRIS Medical Instruments, Inc. In 1996, we changed our name to IRIDEX Corporation and reincorporated in Delaware. Our executive offices are located at 1212 Terra Bella Avenue, Mountain View, California 94043-1824, and our telephone number is (650) 940-4700. We can also be reached at our website at [www.iridex.com](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.

### **The IRIDEX Strategy**

We are one of the worldwide leaders in developing, manufacturing, marketing, selling and servicing innovative medical laser systems. We have three key elements in our strategy: 1) leveraging our core business and increasing recurring revenues, 2) broadening our product lines through product innovation, and 3) developing new market opportunities through strategic alliances, OEM relationships and acquisitions:

**1. Leverage our Core Business and Increase Recurring Revenues.** We believe that we can continue to grow our current installed base of more than 7,775 IRIDEX laser systems worldwide. With the initiatives of our expanded sales and marketing team, we expect to grow the current product offering by double digit growth in laser systems, delivery devices and disposables. Despite the fact that the majority of our sales are a replacement market, the features of our laser systems and new innovations will allow us to increase our market share.

Our business includes a recurring revenue component which includes the sale of our disposable, single use laser probes, EndoProbes, combined with the repair, servicing and extended warranty protection for our laser systems. In 2005 recurring revenues were 36% of the overall business up from 33% in 2004. With our new sales and marketing programs, we believe that there is an opportunity to significantly increase our recurring revenues over the next several years. Our new sales programs include an increase in the number of our domestic area sales managers from 6 to 10 focused on the entire ophthalmic product offering and their incentive plan is more focused on the recurring revenue opportunity. Our new U.S. marketing programs include a VIP (Valued IRIDEX Partner) program which allows customers to access additional IRIDEX products through a contractual arrangement on the purchase of disposable laser probes. During the past two years, we have

introduced many different types of EndoProbes into the market, including our stepped, intuitive and illuminating probes.

When a customer purchases our laser system, a warranty is included. In addition, we market extended warranty protection plans which can be purchased at the time of original acquisition or after the expiration of the warranty. We also repair products out of warranty under a program which allows our customer to obtain a laser overnight while their unit is returned for repair. The customer is charged normal and reasonable charges for these services.

**2. Broaden Product Lines through Product Innovation.** One of our core strengths has been our regular introduction of new laser systems, delivery devices and product upgrades to enhance the benefits of our laser systems. We attempt to leverage our existing products and technology when developing new products. In 1997, we introduced the DioLite 532, based on the same visible (green) light technology as the OcuLight GL, for the dermatology market. In 1998, we introduced the OcuLight GLx, a new version of the OcuLight GL, with increased power and delivery device capability. In October 1999, we introduced the next generation of OcuLight SLx, which offers added features to our OcuLight SL, such as LongPulse and MicroPulse operating modes. These features enable the OcuLight SLx to perform the latest in clinical infrared applications. In October 2000, we introduced the EasyFit family of portable slit lamp adapters (or SLAs), which allow for improved viewing clarity of the retina by the physician. In 2001, we introduced the Apex 800, a high powered infrared laser for hair removal for the dermatology market. In October 2002, we introduced the OcuLight Symphony Laser Delivery System which combines the clinical versatility and convenience of infrared and visible photocoagulation consoles into one delivery device. We also introduced an expanded EndoProbe product line and a 5 millimeter Large Spot Slit Lamp Adapter. In December 2002, we commenced shipment of the Millennium Endolase module, which we manufacture to be included in Bausch & Lomb's Millennium Microsurgical System. In 2003, we introduced a 50 micron spot slit lamp adapter, the smallest spot size diameter available on IRIDEX slit lamp adapters. In addition, in 2003 and the first quarter of 2004, we introduced four additions to our Endoprobe product line. In 2004, we launched a new, menu driven infrared platform for ophthalmology, the IQ810, designed to allow easier physician access to a variety of advanced laser energy delivery modes used to perform Minimum Intensity Photocoagulation (MIP) procedures. The IQ810 platform also includes some new delivery devices such as IQ Slit Lamp Adapter with Fiber Check and accessories such as the SmartControl footswitch and remote control. For the dermatology market, we introduced the VariLite, a dual wavelength laser in the fourth quarter of 2004 that offers both high power 532 nm and 940 nm wavelengths for added clinical versatility and convenience for the physician. In 2005, we continued to expand our disposable EndoProbe product line with new designs in stepped probes, intuitive probes and illuminating probes. In 2005, we also launched the DioLite XP laser which is a high power 532 nm wavelength laser and ScanLite XP scanner for dermatological applications. The DioLite XP laser offers increased power to optimize clinical performance. The ScanLite XP scanner offers a large scan area. The combination of high power and large scan size allows physicians to optimize treatments while covering twice the treatment area in half the time. The characteristics of these new products since 1997 are similar to those which have made our previous products successful, such as low cost ownership, reliability and portability. We intend to continue our investment in research and product innovation to improve the performance of our systems and broaden our product offerings. We also intend to develop innovative technologies which can address the customer needs of the ophthalmic and dermatology markets.

**3. Develop New Market Opportunities Through Strategic Alliances, OEM Relationships and Acquisitions.** Based upon our core competencies, we intend to establish strategic alliances and/or OEM relationships in order to bring new products to market which can help improve gross margins. As an

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example, in October 2002, we announced our collaboration with Bausch & Lomb to design and manufacture a solid-state green light laser photocoagulator module 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 designed to be sold as a stand-alone product. We intend to pursue additional strategic alliances and OEM relationships in medical segments other than ophthalmology and dermatology. Our targets will be companies that currently serve medical markets in which our technology can be utilized. This would allow these companies to add therapeutic based laser products to their product portfolios creating an opportunity to leverage their current strengths in those markets. Some of these markets could include cardiovascular, urological and dental.

In order to achieve the desired level of growth, we must explore opportunities to acquire technologies or companies which strategically fit our current core competencies. We have an excellent reputation, within the retinal segment of ophthalmology, as a company with innovative and reliable technology combined with responsive customer service. Given the level of management experience within the company and the size of the market opportunity, an acquisition within ophthalmology would be a good fit strategically. See "Management's Discussion and Analysis of Financial Condition and Results of Operations – Factors That May Affect Future Results – We Depend on Collaborative Relationships to Develop, Introduce and Market New Products, Product Enhancements and New Applications."

## **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, including disposable 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 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 non-disposable products range in price from \$2,000 to \$60,000, and consist of laser consoles and specialized delivery devices and our line of disposable products with a list price of between \$150 to \$200 to end customers.

*Consoles:* Our laser consoles incorporate the economic and technical benefits of semiconductor laser technology.

*Infrared Photocoagulator Consoles.* These OcuLight and IQ810 photocoagulator consoles used by ophthalmologists are available in two infrared (810nm) output power ranges: the OcuLight SL at 2 Watts and the IQ810 and OcuLight SLx at 3 Watts. Each console weighs 14 pounds, has dimensions of 4"H x 12"W x 12"D, and requires no external air or water cooling. We believe that the smaller overall sizes, lower weights and low power requirements to operate represent distinct advantages over competing products.

*Visible (or Green) Photocoagulator Consoles.* Our OcuLight OR, GL and OcuLight GLx semiconductor-based photocoagulator consoles used in ophthalmology deliver visible (532nm) laser light. The OcuLight GLx has increased power and delivery device capability. Our visible laser light dermatology products, the DioLite XP and DioLite 532 are also based on semiconductor-based technology. The OcuLight OR/GL/GLx/DioLite XP/DioLite consoles weigh 15 pounds, have dimensions of 6"H x 12"W x 12"D, draw a maximum of 300 Watts of wall power and require no external air or 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



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of microsurgical capabilities for the vitrectomy procedure. The Millennium Endolase module is compatible with the IRIDEX disposable EndoProbe handpieces and Laser Indirect Ophthalmoscope.

*Combination Infrared/Visible Photocoagulator Consoles.* The OcuLight Symphony Laser Delivery System, is used by ophthalmologists and consists of an OcuLight SLx infrared (810nm) laser console, OcuLight GLx green (532 nm) laser console, multi-fiber slit lamp adapter, slit lamp and a custom cart. The OcuLight Symphony Laser Delivery System combines the clinical versatility and convenience of a 532 nm, 810 nm and large spot 810 nm into one delivery device for retinal photocoagulation and glaucoma procedures. Our VariLite product which is used in dermatology is a dual wavelength combination of 532nm and infrared 940nm. The VariLite wavelength can be changed with just the flip of a single switch and can be used in conjunction with the ScanLite as well as several different sized handpieces. We believe that this product offers a unique value-added proposition and the efficiency of dual laser wavelength delivery in a single product.

*Specialized 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 this product can add capabilities by simply purchasing new interchangeable delivery devices and utilizing them with their existing console. We have developed both disposable and nondisposable delivery devices and expect to continue to develop additional devices.

*Ophthalmic 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. In 2003, we introduced a 50 micron spot slit lamp adapter, a reduction in the smallest spot size diameter available on IRIDEX slit lamp adapters.

*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.* The EndoProbe or laser probe is 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, fluted, illuminating, stepped, endocular and intuitive 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 the eye. The G-Probe's non-invasive procedure takes approximately ten minutes, is done to 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 disposable product.

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*DioPexy Probe.* The DioPexy Probe is a hand-held instrument which is used in procedures to treat retinal tears and breaks, noninvasively 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.

***Dermatology Delivery Devices:***

*DioLite Handpiece.* The DioLite Handpiece is a hand held instrument that is used in the treatment of vascular and pigmented skin lesions. These devices are available in 200, 500, 700, 1000 and 1400 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 removal. Ergonomic handpieces can be used with both the 532 nm and 940 nm wavelengths and are available in 0.7, 1.0, 1.4, 2.0 and 2.8 spot sizes.

*ScanLite Scanner.* The ScanLite XP and ScanLite are computer pattern generators with integrated controls designed to enhance the capabilities of the DioLite XP and DioLite 532 laser systems. They allow rapid and uniform treatment of large-area vascular and pigmented skin lesions including port wine stains, matted telangiectasia, and cafe au lait stains.

The following chart lists the eye disease procedures that can utilize our photocoagulator systems, including the console and delivery devices that we offer for use in treating these diseases. The selection of delivery device is often determined by the severity and location of the disease. These diseases are treated either within the physician’s office, clinic, or the operating room.

***Ophthalmology Treatments:***

<u>Condition</u>	<u>Procedure</u>	<u>Console</u>	<u>Delivery Devices</u>
Age-related Macular Degeneration	Retinal Photocoagulation	Infrared & Visible	Slit Lamp Adapter
Diabetic Retinopathy			
Macular Edema	Grid Retinal Photocoagulation	Infrared & Visible	Slit Lamp Adapter & Operating Microscope Adapter, Slit Lamp 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	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 Indirect Ophthalmoscope
Macular Holes	Vitrectomy Procedure	Visible	EndoProbe*

\* Disposable single use products

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

***Dermatology Treatments:***

<u>Condition</u>	<u>Procedure</u>	<u>Console</u>	<u>Delivery Devices</u>
Vascular Lesions	Selective Photothermolysis	Visible	DioLite Handpiece
Pigmented Lesions	Selective Photothermolysis	Visible	DioLite Handpiece



## **Research and Product Innovation**

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 product innovation (formerly known as product development) activities are performed by a current team of 17 engineers with an average of 22 years of experience each in medical products, laser systems and delivery devices. The core competencies of the team include: mechanical engineering, electrical engineering, optics, software, firmware or delivery devices. The team is being transitioned with a focus to introduce innovative products which satisfy the unmet and emerging needs of our customers. Their approach is a rapid product development process which integrates all the necessary disciplines of the company from product inception through customer acceptance. This approach should allow for rapid and reliable new product innovations and a consistent pipeline of innovative products for our customers.

Our research activities are performed internally by our research staff. From time to time, we supplement our internal research staff by hiring consultants and/or universities with specialized expertise. Research efforts are directed toward the development of new products and new applications for our existing products, as well as the identification of markets which may include clinical trials and may not be currently addressed by our products.

We are supporting pre-clinical and clinical studies to develop new photocoagulation treatments and applications using Minimal Intensity Photocoagulation (MIP) protocols. MIP is a laser treatment approach pioneered by IRIDEX which uses our OcuLight SLx infrared lasers to maximize

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preservation of sensitive retinal tissues while stimulating a therapeutic effect. We believe that maintaining a position in MIP will allow us to make a substantial contribution in the treatment of serious eye diseases such as age-related macular degeneration, diabetic retinopathy and glaucoma.

The objectives of developing new photocoagulation treatments and applications are to expand the number of patients who can be treated, to more effectively treat diseases, to treat patients earlier in the treatment regimen and to reduce the side-effects of treatment. Examples of such studies with regard to particular eye afflictions are included in the following paragraphs.

*Age-Related Macular Degeneration (AMD) – Wet Form.* AMD is a progressive disease that damages the central vision and affects a person's ability to read, see faces, and drive. About 50 million people worldwide have AMD and, of these, about 5 million have the more severe wet form. Though the wet form of AMD constitutes about 10% of all AMD, it accounts for about 80% of all severe vision loss associated with AMD. We are pursuing several approaches to treat wet AMD at different stages. All of these approaches close new blood vessels in the eye's macula caused by wet AMD with less damage than conventional laser treatments. One approach is Transpupillary Thermotherapy (TTT). TTT is a MIP protocol that uses a milder form of retinal photocoagulation to treat wet AMD while sparing the sensory retina, as compared to conventional laser photocoagulation techniques. The protocol uses the OcuLight SLx laser and Large Spot Slit Lamp Adapter to produce favorable therapeutic responses with minimal side effects and preservation of vision in patients with occult choroidal neovascularization (CNV) secondary to AMD. In October 2004, we announced that the preliminary visual outcome data in the intent-to-treat evaluation of the Company supported TTT4CNV clinical trial showed that TTT, as applied in this trial, while trending favorably, did not result in a statistically significant beneficial effect relative to an untreated control group. Since that time, results of subgroup analysis have demonstrated a statistically significant benefit in a subgroup of patients with baseline visual acuity of 20/100 or worse. 22% of treated eyes improved vision by one or more lines compared with none of the eyes in the untreated control group. Furthermore, at 18 months, there was a 2 line benefit in preserving vision in this subgroup when compared to sham treated eyes. Both of these trends were statistically significant. A paper is expected to be published during 2006.

*Age-Related Macular Degeneration – Dry Form.* About 90% of AMD is the dry form. Our approach to the treatment of dry AMD is to preserve or improve vision by following a MIP protocol that uses the OcuLight infrared laser to cause resorption of dry AMD deposits (drusen) which have accumulated in the macula. We are supporting a multi-center clinical trial which is testing a treatment of eyes with dry age-related macular degeneration (PTAMD trial). At the American Academy of Ophthalmology meeting in October 2005 Dr. Thomas Friberg presented initial results from the PTAMD Bilateral Study. In the PTAMD Bilateral Study an eligible patient must have had dry AMD (at least 5 drusen) in both eyes and have visual acuity between 20/20 and 20/63. One eye was randomized to sub-threshold (MIP) treatment with the 810 nm diode laser and the other eye observed. 639 patients or 1278 eyes were enrolled in the study and followed for up to 5 years. The PTAMD tried to answer two questions: First, was there a prophylactic benefit from a single subthreshold laser treatment in slowing the progression of AMD from dry (drusen) to wet (CNV)? Secondly, was there a therapeutic benefit from a single subthreshold laser treatment in drusen reduction and vision in these eyes? In answering these two questions: (1) the initial study results showed no benefit in prophylaxis. There was no indication of a beneficial prophylactic treatment effect on CNV occurrence; and there was no trend toward a beneficial effect (P=0.63); (2) the study did show a therapeutic benefit in drusen reduction and vision in treated eyes. Drusen significantly reduced after a single sub-threshold infrared laser treatment. At 12 months following treatment 44.5% of treated

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eyes had a significant reduction in drusen compared to 4.5% of observed eyes ( $P < 0.0001$ ). In all eyes enrolled visual acuity changes showed some indication of a beneficial effect of treatment at 18 months and onward. At month 24: Treated eyes showed a 1.5 letter beneficial difference in VA compared to the observed eye ( $P = 0.04$ ). Treated eyes also had a higher percentage (12% vs. 8%) showing a 2 or more line gain. In a sub-group of eyes with 20/30 or worse baseline VA the beneficial effect treatment was more pronounced. At month 24: Treated eyes showed a 4.0 letter (1 line) beneficial difference in VA with treated eyes improving 2.9 letters and observed eyes losing 1.1 letters ( $P = 0.0034$ ); Treated eyes had a higher percentage (31% vs. 19%) showing a 2 or more line gain; Treated eyes also had a lower percentage (13% vs. 22%) showing a 2 or more line loss. We expect additional reports to be released in 2006.

*Glaucoma.* Preliminary studies are underway to evaluate the use of the G-Probe as a primary surgical treatment modality for glaucoma in various parts of the world.

*Diabetic Retinopathy.* Other MIP studies are underway to investigate the treatment of diabetic retinopathy using the MicroPulse operating mode available in our OcuLight SLx product with the objective of causing regression of the disease with less loss of vision than conventional laser therapy.

*Ocular Tumors.* Clinical studies have reported successful treatment of ocular tumors using OcuLight infrared lasers using the TTT approach.

All of these clinical projects should be considered in the research area and they may or may not result in additional commercial opportunities. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Factors That May Affect Future Results – We are Dependent on the Successful Outcome of Clinical Trials of Our Products and New Applications Using Our Products”.

### **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, surgi-centers and hospitals. No customer or distributor accounted for 10% or more of total sales in any of 2005, 2004 or 2003. See Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

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 15,000-20,000 ophthalmologists in the United States and 40,000-60,000 internationally who are each potential customers. Additionally, we estimate that there are approximately 4,900 and 18,000 hospitals in the United States and internationally, respectively, as well as approximately 4,000 ambulatory surgical centers in the United States which potentially represent multiple unit sales. We believe there are approximately 10,000 dermatologists and approximately 9,000 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 affiliation with hospitals or other medical centers, each independent ophthalmologist, dermatologist, plastic surgeon, office, hospital and medical center is a potential customer for our products. We are seeking to broaden our customer base by developing new products directed at addressing the needs of ophthalmologists and dermatologists.

We seek to provide superior customer support and service and therefore created our Global Customer Care Group with the responsibility for our customer requests and product repairs, which has resulted in a significant improvement in our response times to customer support and service issues. We believe that our superior customer service and technical support distinguish our product offerings from those of our

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competitors. 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 product cannot be diagnosed and resolved by telephone, a replacement unit is shipped overnight to any domestic customer and by the most rapid delivery means available to any international customer, 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 market our products in the United States predominantly through our direct sales force. Our direct sales force of 18 employees are engaged in sales efforts within the United States. Our sales and marketing organization is based at our corporate headquarters in Mountain View, California with area sales managers located throughout the United States.

International product sales represented 38.6%, 39.4% and 36.7% of our sales in 2005, 2004 and 2003, 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, Pacific Rim, Middle East and Latin America. Our products are sold internationally through our 77 independent distributors into 107 countries. 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 on 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 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Factors That May Affect Future Results—We Depend on International Sales.”

To support our sales process, we conduct marketing programs which include direct mail, trade shows, public relations, market research, and advertising in trade and academic journals and newsletters. We annually participate in approximately 160 trade shows internationally. These meetings allow us to present our products to existing and prospective buyers. One of our new marketing programs includes a VIP (Valued IRIDEX Partner) program which allows customers to access additional IRIDEX products through a contractual agreement on the purchase of disposable laser probes. In 2005, recurring revenues (including sales of EndoProbes and service revenue) were 36% of the overall business up from 33% in 2004. During the past two years, we have introduced many different types of EndoProbes into the market, including our new stepped, intuitive and illuminating probes.

We believe that educating patients and physicians at an early stage about the long-term health benefits and cost-effectiveness of diagnosis and treatment of diseases that cause blindness is critical to market acceptance of our ophthalmic products. The trend toward management of health care costs in the United States should lead to increased awareness of and early intervention of disease management with cost-effective treatments and, as a result, will increase demand for our ophthalmic products. Our marketing efforts are made to promote the education of our customers on these topics.

Through marketing, we collaborate with our customers to enhance our ability to identify new applications for our products, validate new procedures using our products and identify new product applications which help meet their unmet needs. 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

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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 December 31, 2005, 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 (the "FDA"). In April 1998, we received certification for ISO 9001/EN 46001. ISO 9001/EN 46001 is a documented 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.

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 and 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 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations—Factors That May Affect Future Results—We Face Risks of Manufacturing and We Depend on Key Manufacturers and 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 under Annex II guidelines, the most stringent path to CE certification. With Annex II CE certification, we have demonstrated our ability to both understand and comply with all applicable European standards. 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 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations – Factors That May Affect Future Results-We Are Subject to Government Regulation."

### **Competition**

Competition in the market for laser systems and delivery devices used for ophthalmic and dermatology treatment procedures is intense and is expected to increase. This market is also characterized by rapid technological innovation and change, and our products could become obsolete as a result of future innovations. Our competitive position depends on a number of factors including product performance, characteristics and functionality, ease of use, scalability, durability and cost. In addition to other companies that manufacture photocoagulators and dermatological devices, we compete with pharmaceutical solutions, other technologies and other surgical techniques available in both the dermatologic and ophthalmic markets. Our principal competitors in ophthalmology are Lumenis Ltd., Nidek, Inc., Carl Zeiss Meditec AG, Alcon Inc. and Synergetics. All of these companies currently offer a competitive, semiconductor-based laser system for ophthalmology. Also within ophthalmology pharmaceutical alternative treatments for AMD such as Visudyne (Novartis), Macugen (Eyetechnology) and Lucentis (Genentech) compete rigorously with traditional laser procedures. Our principal competitors in dermatology are Palomar Technologies, Candela Corporation,



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Syneron, Lumenis Ltd., and Laserscope. Some 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 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Factors That May Affect Future Results—Our Market is Competitive.”

### **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 15 United States patents and five foreign patents on the technologies related to our products and processes, which have expiration dates ranging from 2009 to 2023. We have approximately five pending patent applications in the United States and five 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 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Factors That May Affect Future Results – We Rely on Patents and Proprietary Rights.”

### **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 premarket 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 device manufactured or distributed by us.

In the United States, medical devices are classified into one of three classes (Class I, II or III), on the basis of the controls deemed necessary by the FDA to reasonably assure the safety and effectiveness of such products. Under FDA regulations, Class I devices are subject to general controls (for example, labeling, premarket notification and adherence to Quality System Regulations (“QSRs”) requirements). Class II

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devices are subject to general and special controls (for example, performance standards, postmarket surveillance, patient registries, and FDA guidelines). Generally, Class III devices are those which must receive premarket approval (or “PMA”) by the FDA to ensure their safety and effectiveness.

Unless otherwise exempt, before a new device can be introduced into the market, the manufacturer must obtain marketing clearance through either a 510(k) premarket notification or a PMA. 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 IQ810 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.

A PMA application must be submitted if a proposed device is not substantially equivalent to a legally marketed Class I or Class II device, or if it is a Class III device for which the FDA has called for PMAs. A PMA application must be supported by valid scientific evidence which typically includes extensive data, including human clinical trial data, to demonstrate the safety and effectiveness of the device. The PMA application must also contain the results of all relevant bench tests, laboratory and animal studies, a complete description of the device and its components, and a detailed description of the methods, facilities and controls used to manufacture the device. In addition, the submission must also contain the proposed labeling, advertising literature and training methods.

Upon receipt of a PMA application, the FDA makes a threshold determination as to whether the application is sufficiently complete to permit a substantive review. If the FDA determines that the PMA application is sufficiently complete to permit a substantive review, the FDA will accept the application for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the PMA. An FDA review of a PMA application generally takes one to two years from the date the PMA application is accepted for filing, but may take significantly longer. The review time is often significantly extended as a result of the FDA asking for more information or clarification of information already provided in the submission. During the review period, an advisory committee, typically a panel of clinicians, will likely be convened to review and evaluate the application and provide recommendations to the FDA as to whether the device should be approved. The FDA is not bound by the recommendations of the advisory panel. Toward the end of the PMA review process, the FDA generally will conduct an inspection of the manufacturer’s facilities to ensure that the facilities are in compliance with applicable QSR requirements.

If the FDA’s evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which may contain a number of

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conditions which must be met in order to secure final approval of the PMA. When, and if, those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter, authorizing commercial marketing of the device for certain indications. The FDA may also determine that additional clinical trials are necessary or other deficiencies exist in the PMA, in which case PMA approval may be delayed. The PMA process can be expensive, uncertain and lengthy, and a number of devices for which the FDA approval has been sought by other companies have never been approved for marketing.

If human clinical trials of a device are required in connection with either a 510(k) notification or a PMA, and the device presents a “significant risk,” the sponsor of the trial (usually the manufacturer or the distributor of the device) is required to file an investigational device exemption (“IDE”) application prior to commencing human clinical trials. The IDE application must be supported by data, typically including the results of animal and laboratory testing. If the IDE application is reviewed and approved by the FDA and one or more appropriate institutional review boards (“IRBs”), human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a “nonsignificant risk” to the patient, a sponsor may begin the clinical trial after obtaining approval for the study by one or more appropriate IRBs.

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 premarket 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.

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.

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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 premarket 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 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 dermatologic products because dermatology procedures, in general, are not covered under most insurance programs and the cost of these procedures are paid for by the patient.

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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 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations – Factors That May Affect Future Results – We Depend on Third Party Coverage and Reimbursement Policies."

Doctors, clinics, hospitals and other users of our products may not obtain adequate reimbursement for use of our products from third-party payers. While we believe that the laser procedures using our products have generally been reimbursed, payers may deny coverage and reimbursement for our products if they determine that the device was not reasonable and necessary for the purpose used, was investigational or was not cost-effective.

### **Product Liability and Insurance**

We may be subject to product liability claims in the future. Our products are highly complex and are used to treat extremely delicate eye tissue and skin conditions on and near a patient's face. Our products are often used in situations where there is a high risk of serious injury or adverse side effects. In addition, although we recommend that our disposable products only be used once and prominently label these disposables, we believe that certain customers may nevertheless reuse these disposable products. If a disposable product is not adequately sterilized by the customer between such uses, a patient could suffer serious consequences, possibly resulting in a suit against us for damages. Accordingly, the manufacture and sale of medical products entails significant risk of product liability claims. Although we currently maintain and intend to continue the Company's product liability insurance, adequate insurance may not be available on acceptable terms, if at all and may not provide adequate coverage against potential liabilities. Such insurance is expensive and in the future may not be available on acceptable terms, 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. To date, we have not experienced any product liability claims which would result in payments in excess of our policy limits.

### **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 December 31, 2005, we had a total of 114 full-time employees, including 51 in operations, 31 in sales and marketing, 17 in research and product innovation 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 December 31, 2005, we employed 2 such persons. We intend to hire additional personnel during the next twelve months primarily in the direct sales and production areas. 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.iredex.com](http://www.iredex.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.

### **Item 2. Properties**

Our operating facilities are located in 37,000 square feet of space in Mountain View, California. This facility is being substantially utilized for all of our manufacturing and research and development efforts and serves as our headquarter offices. This facility is utilized for both our ophthalmology medical device segment and our dermatology medical device segment. We lease these facilities and in September 2003, we entered into a lease amendment for our facility in Mountain View. The original lease term of this facility, which ended in February 2004, was amended and extended until February 2009. The lease was also amended to grant us an option to renew this lease for an additional five year period beginning 2009 and continuing until 2014 at a base monthly rental amount to be negotiated at the time of the renewal.

Management believes that our facility has capacity adequate for our current needs and that suitable additional space or alternative space will be available as needed in the future on commercially reasonable terms.

### **Item 3. Legal Proceedings**

In October 2005, the Company filed a suit against Synergetics, USA, Inc. for infringement of a patent. The Company seeks injunctive relief, monetary damages, treble damages, cost and attorneys' fees. Synergetics answered the Company's complaint in November 2005 and denied liability for patent infringement, filing counterclaims seeking a declaratory judgment that it did not infringe the Company's patent. Synergetics also brought three additional counterclaims for false advertising, commercial disparagement, trade libel, injurious falsehood, unfair competition, disparagement of property, slander of goods and defamation, under state and federal law, based upon allegations that the Company had raised safety issues involving Synergetics' product with the Food and Drug Administration and the public. Synergetics seeks monetary damages, costs and attorneys' fees. Our response to these counterclaims was a denial of any wrongdoing and a reference to the expiration of the statute of limitations on those claims. Management believes that liabilities resulting from such proceedings, or 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. While we believe it's not material to the company's operations, the company may incur significant dedication of management resources and legal costs in connection with this lawsuit.

### **Item 4. Submission of Matters to a Vote of Security Holders**

Not applicable.

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

Our common stock is quoted on the NASDAQ National Market under the symbol "IRIX" 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 National Market.

	<u>High</u>	<u>Low</u>
<b>Fiscal 2006</b>		
First Quarter (through March 23, 2006)	\$11.49	\$7.98
<b>Fiscal 2005</b>		
First Quarter	\$ 6.19	\$4.21
Second Quarter	6.53	5.07
Third Quarter	8.80	6.16
Fourth Quarter	8.93	6.29
<b>Fiscal 2004</b>		
First Quarter	\$ 9.17	\$5.09
Second Quarter	9.15	6.08
Third Quarter	7.05	5.82
Fourth Quarter	7.19	3.80

**Fiscal 2005**

On March 23, 2006, the closing price on the NASDAQ National Market for our common stock was \$10.94 per share. As of March 23, 2006, there were approximately 73 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 bank line of credit. See Note 4 of Notes to Consolidated Financial Statements.

[Table of Contents](#)**Securities Authorized for Issuance Under Equity Compensation Plans**

As of December 31, 2005, we had three equity compensation plans. These plans are the 2005 Employee Stock Purchase Plan, 1995 Director Option Plan and 1998 Stock Option Plan, all of which have been approved by our stockholders. The following table summarizes our equity compensation plans as of December 31, 2005:

Plan category	(a) Number of securities to be issued upon exercise of outstanding options, warrants and rights	(b) Weighted-average exercise price of outstanding options, warrants and rights	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders	1,894,899(1)	\$ 5.50	353,338(2)
Equity compensation plans not approved by security holders	259,104(3)	6.07	0
<b>Total</b>	<b>2,154,003</b>	<b>\$ 5.56</b>	<b>353,338</b>

- (1) Includes 1,382,935 options to purchase shares outstanding under the 1998 Stock Plan, 101,250 options to purchase shares outstanding under the 1995 Director Option Plan and 410,714, options to purchase shares outstanding under the Amended and Restated 1989 Incentive Stock Plan.
- (2) Includes 295,516 options available for future issuance under the 1998 Stock Plan and 57,822 shares issuable under the 2005 Employee Stock Purchase Plan.
- (3) Consists of two items. The first is a Stand-Alone Option granted to Barry G. Caldwell on July 5, 2005, entitling Mr. Caldwell to purchase up to 234, 104 shares of the Company's common stock at an exercise price of \$6.07 per share, issued as a stand-alone option, outside of the Company's existing stock plans and as a material inducement to Mr. Caldwell accepting employment with the Company. The shares covered by the Stand-Alone Option vest over a four (4) year period, with 1/4<sup>th</sup> of the total number of shares subject to the Stand-Alone Option vesting on July 5, 2006 and 1/48<sup>th</sup> of the total number of shares subject to the Stand-Alone Option vesting each full month thereafter, provided that Mr. Caldwell continues to be a service provider to the Company on each such date.

The second item is a warrant, issued in conjunction with the employment of the Company's Chief Executive Officer, in consideration of services performed under a recruiting contract, to purchase 25,000 shares of the Company's common stock at an exercise price of \$6.07 per share. The warrant is exercisable at any time and expires on July 5, 2008.



[Table of Contents](#)**Item 6. Selected Financial Data**

The following selected consolidated financial data as of December 31, 2005 and January 1, 2005, and for the years ended December 31, 2005, January 1, 2005 and January 3, 2004, has been derived from, and are qualified by reference to, our audited consolidated financial statements included herein. The selected consolidated statement of operations data for the years ended December 28, 2002 and December 29, 2001 and the consolidated balance sheet data as of January 3, 2004, December 28, 2002 and December 29, 2001 has been derived from our audited financial statements not included herein. These historical results are not necessarily indicative of the results of operations to be expected for any future period.

The data set forth below (in thousands, except per share data) are qualified by reference to, and should be read in conjunction with Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," and our consolidated financial statements, related financial statement notes and other financial information included in Item 8, "Financial Statements and Supplementary Data."

	Fiscal Year 2005	Fiscal Year 2004	Fiscal Year 2003	Fiscal Year 2002	Fiscal Year 2001
<b>Consolidated Statement of Operations</b>					
<b>Data:</b>					
Sales	\$ 37,029	\$ 32,810	\$ 31,699	\$ 30,634	\$ 27,275
Cost of sales	18,854	17,922	17,628	17,046	14,205
Gross profit	18,175	14,888	14,071	13,588	13,070
Operating expenses:					
Research and development	4,195	4,509	4,032	4,315	4,808
Selling, general and administrative	12,171	11,455	10,087	9,454	10,251
Total operating expenses	16,366	15,964	14,119	13,769	15,059
Income (loss) from operations	1,809	(1,076)	(48)	(181)	(1,989)
Interest and other income, net	528	319	212	122	426
Income (loss) before income taxes	2,337	(757)	164	(59)	(1,563)
Benefit from (provision for) income taxes	(666)	355	207	209	962
Income (loss) from continuing operations	1,671	(402)	371	150	(601)
Income (loss) from operations of discontinued Laser Research segment (net of applicable income tax benefit (provision) of \$0, \$0, \$0, \$0 and \$124 respectively)	—	—	—	—	(204)
Loss on disposal of Laser Research segment (net of applicable income tax benefit of \$0, \$0, \$0, \$0 and \$315 respectively)	—	—	—	—	(468)
Net income (loss)	\$ 1,671	\$ (402)	\$ 371	\$ 150	\$ (1,273)
Basic net income (loss) per common share:					
Continuing operations	\$ 0.23	\$ (0.06)	\$ 0.05	\$ 0.02	\$ (0.09)
Discontinued operations	—	—	—	—	(0.10)
Basic net income (loss) per common share	\$ 0.23	\$ (0.06)	\$ 0.05	\$ 0.02	\$ (0.19)
Diluted net income (loss) per common share:					
Continuing operations	\$ 0.21	\$ (0.06)	\$ 0.05	\$ 0.02	\$ (0.09)
Discontinued operations	—	—	—	—	(0.10)
Diluted net income (loss) per common share	\$ 0.21	\$ (0.06)	\$ 0.05	\$ 0.02	\$ (0.19)
Shares used in net income (loss) per common share basic calculations					
	7,405	7,200	6,933	6,870	6,757
Shares used in net income (loss) per common share diluted calculations					
	7,880	7,200	7,072	6,928	6,757

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	December 31, 2005	January 1, 2005	January 3, 2004	December 28, 2002	December 29, 2001
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and available-for-sale securities	\$21,434	\$18,028	\$16,292	\$11,542	\$ 9,102
Working capital	32,330	25,342	28,462	28,072	26,374
Total assets	41,104	39,093	35,839	34,272	33,788
Total stockholders' equity	34,517	31,783	30,834	30,198	29,833

## 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 and delivery devices used to treat eye diseases in ophthalmology and skin conditions in dermatology (aesthetics). Our products are sold in the United States predominantly through a direct sales force and internationally through 77 independent distributors into 107 countries. Total product sales in 2005, 2004, and 2003 were \$37.0 million, \$32.8 million, and \$31.7 million respectively.

Our revenues arise primarily from the sale of our IRIS Medical OcuLight Systems, IQ810 lasers, VariLite, DioLite 532 systems, delivery devices, disposables and revenues from service and support activities. Our current family of OcuLight systems includes the IRIS Medical OcuLight Symphony, OcuLight SL, OcuLight SLx, OcuLight GL and OcuLight GLx laser photocoagulation systems as well as the IQ810 laser. We also produce the Millennium Endolase module which is sold exclusively to Bausch & Lomb and incorporated into their Millennium Microsurgical System. We believe that our future growth in revenue will be based upon the successful implementation of our strategy in these areas: 1) leveraging our core business and increasing recurring revenues, 2) broadening our product lines through product innovation, and 3) developing new market opportunities through strategic alliances, OEM relationships and acquisitions.

Our business includes a recurring revenue component which includes the sale of our disposable single use laser probes, EndoProbes, combined with the repair, servicing and extended warranty protection for our laser systems. In 2005, recurring revenues were 36% of the overall business up from 33% in 2004. With our new sales and marketing programs, combined with having sold more than 7,775 IRIDEX laser systems worldwide, we believe that there is an opportunity to significantly increase our recurring revenues over the next several years. Our new sales programs include an increase in the number of our domestic area sales managers from 6 to 10 focused on the entire ophthalmic product offering and their incentive plan is more focused on the recurring revenue opportunity. Our new marketing programs include a VIP (Valued IRIDEX Partner) program which allows customers to access additional IRIDEX products through a contractual agreement on the purchase of disposable laser probes. During the past two years, we have introduced many different types of EndoProbes into the market, including our new stepped, intuitive and illuminating probes.

Sales to international distributors are made on open credit terms or letters of credit. Sales of our products internationally currently are denominated in United States dollars and, accordingly, are subject to risks associated with international monetary conditions and currency fluctuations. In general, strengthening of the U.S. dollar relative to a foreign currency increases the cost of our product to our international customers. Other risks that international sales are subject to include shipping delays, generally longer receivable collection periods, changes in applicable regulatory policies, domestic and foreign tax policies, trade restrictions, duties and tariffs and economic and political instability. Future currency fluctuations or other factors discussed above may have a material adverse effect on our business, financial condition or results of operation. See "—Factors That May Affect Future Results—We Depend on International Sales for a Significant Portion of Our Operating Results."

Cost of sales consists primarily of the cost of purchasing components and sub-systems, assembling, packaging, shipping and testing components at our facility, and the direct labor and associated overhead. Research and development expenses consist primarily of personnel costs, materials and research support provided to clinicians at medical institutions developing new applications which utilize our products. Research and development costs have been expensed as incurred. Sales, general and administrative expenses consist primarily of costs of personnel, sales commissions, travel expenses, advertising and promotional expenses, facilities, legal and accounting, insurance and other expenses which are not allocated to other departments.

### Results of Operations

The following table sets forth certain operating data as a percentage of sales for the periods indicated:

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	Year Ended December 31, 2005	Year Ended January 1, 2005	Year Ended January 3, 2004
Sales	100%	100%	100.0%
Cost of sales	50.9	54.6	55.6
Gross profit	49.1	45.4	44.4
Operating expenses:			
Research and development	11.3	13.7	12.7
Sales, general and administrative	32.9	35.0	31.8
Total operating expenses	44.2	48.7	44.5
Operating income (loss)	4.9	(3.3)	(0.1)
Other income, net	1.4	1.0	0.7
Income (loss) before income taxes	6.3	(2.3)	0.6
Benefit from (provision for) income taxes	(1.8)	1.1	0.7
Net income (loss)	4.5%	(1.2%)	1.3%

The following table sets forth for the years indicated the amount of sales (in thousands) for our operating segments and sales as a percentage of total sales.

	Year Ended December 31, 2005		Year Ended January 1, 2005		Year Ended January 3, 2004	
	Amount	Percentage of total sales	Amount	Percentage of total sales	Amount	Percentage of total sales
Domestic	\$ 22,713	61.4%	\$ 19,894	60.6%	\$ 20,072	63.3%
International	\$ 14,316	38.6%	\$ 12,916	39.4%	11,627	36.7%
Total	\$ 37,029	100.0%	\$ 32,810	100.0%	\$ 31,699	100.0%
Ophthalmology:						
Domestic	\$ 17,762	48.0%	\$ 16,443	50.1%	\$ 15,724	49.6%
International	\$ 12,901	34.8%	\$ 11,310	34.5%	10,436	32.9%
Total	\$ 30,663	82.8%	\$ 27,753	84.6%	\$ 26,160	82.5%
Dermatology:						
Domestic	\$ 4,951	13.4%	\$ 3,451	10.5%	\$ 4,348	13.7%
International	\$ 1,415	3.8%	\$ 1,606	4.9%	1,191	3.8%
Total	\$ 6,366	17.2%	\$ 5,057	15.4%	\$ 5,539	17.5%

### Ophthalmology and Dermatology Sales Overview

We manage and evaluate our business in two major segments – Ophthalmology and Dermatology. We then further break down these major segments by geography – Domestic (United States) and International (the rest of the world). In addition within Ophthalmology we review trends by laser system sales (laser boxes and delivery devices) and recurring sales (single use disposable probes, Endoprobes combined with the repair, servicing and extended warranty protection for our laser systems). Within the dermatology segment we primarily view macro trends surrounding our laser systems, which include our newly introduced DioLite XP and VariLite laser systems, the DioLite laser system, and the Apex hair removal laser which was discontinued in 2005.

In 2005, sales increased by 12.9% to \$37.0 million from \$32.8 million in 2004. Domestic sales, which represented 61.4% of total sales, increased by 14.2% to \$22.7 million in 2005 from \$19.9 million in 2004. The increase in domestic sales was a result of a \$1.5 million increase in domestic dermatology

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revenue and a \$1.3 million increase in domestic ophthalmology revenue. International sales, which were 38.6% of total sales in 2005, increased by 10.8% to \$14.3 million in 2005 from \$12.9 million in 2004. The increase in international sales was a result of a \$1.6 million increase in international ophthalmology revenue offset by a \$0.2 million decrease in international dermatology revenue.

In 2004, sales increased to \$32.8 million from \$31.7 million in 2003. Domestic sales, decreased by 0.9% to \$19.9 million in 2004 from \$20.1 million in 2003. The decrease in domestic sales was a result of \$0.9 million decrease in domestic dermatology revenue offset by a \$0.7 million increase in domestic ophthalmology revenue. International sales increased by 11.1% to \$12.9 million in 2004 from \$11.6 million in 2003. Both international ophthalmology and dermatology sales increased in 2004, in part, as a result of currency fluctuations. The increase in international ophthalmology sales in 2004 was \$0.9 million while international dermatology sales increased by \$0.4 million.

Overall, with the initiatives of our expanded sales and marketing team, we plan to grow the current product offering by growth in laser systems, delivery devices and disposables.

### *Ophthalmology Sales*

In 2005, ophthalmology sales increased 10.5% to \$30.7 million from \$27.8 million in 2004. The improvement in ophthalmology sales from 2005 to 2004 was primarily a result of a \$2.2 million increase in recurring revenue and a \$0.7 million increase in unit sales of laser systems. Domestic ophthalmology sales increased 8% to \$17.8 million in 2005 from \$16.4 million in 2004. International ophthalmology sales increased 14.1% to \$12.9 million from \$11.3 million in 2004.

In 2004, ophthalmology sales increased to \$27.8 million from \$26.2 million in 2003. The improvement in ophthalmology sales from 2004 to 2003 was primarily a result of a \$1.6 million increase in recurring revenue and a \$0.1 million increase in unit sales of laser systems.

The increase in recurring revenue in both 2005 and 2004 related to our increasing installed base.

Total ophthalmology sales represented 82.8% of our total revenues in 2005, 84.6% of total revenues in 2004, and 82.5% of total revenues in 2003. We believe that this trend established over the past three years should continue and ophthalmic sales should represent approximately 80% of our overall revenues. Domestic ophthalmology sales increased to \$16.4 million in 2004 from \$15.7 million in 2003. International ophthalmology sales increased to \$11.3 million in 2004 from \$10.4 million in 2003. Of the revenues in ophthalmology, approximately 60% are expected from the domestic market and 40% from international markets.

### *Dermatology Sales*

Dermatology sales increased 25.9% in 2005 to \$6.4 million from \$5.1 million in 2004. Domestic dermatology sales increased 43.5% to \$5.0 million in 2005 from \$3.5 million in 2004. The increase in domestic dermatology sales was due primarily to a \$1.1 million increase in unit sales of our newer laser systems (the VariLite and the DioLite XP) and a \$0.2 million increase in dermatology service revenue offset by decreases in unit sales of the DioLite and the Apex laser systems.

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International dermatology sales decreased 11.9% to \$1.4 million in 2005 from \$1.6 million in 2004. The decrease in international dermatology sales was due to a \$0.9 million decrease in unit sales of the Apex hair removal laser which was discontinued in 2005 offset by a \$0.7 million increase in newer laser system sales.

Dermatology sales decreased in 2004 to \$5.1 million from \$5.5 million in 2003. Domestic dermatology sales decreased to \$3.5 million in 2004 from \$4.3 million in 2003. The decrease in domestic dermatology sales was due primarily to a decrease in unit sales of the DioLite laser systems and the Apex hair removal laser and, to a much lesser degree, a slight change in average selling prices of those laser systems. These decreases were offset by new VariLite laser system sales. International dermatology sales increased to \$1.6 million in 2004 from \$1.2 million in 2003.

During the past three years, total dermatology sales represented 17.2% of our total revenues in 2005, 15.4% of total revenues in 2004 and 17.5% of total revenues in 2003. We believe that the trends established in dermatology over the past three years should continue to some degree. We expect that the domestic market will represent approximately 75% of dermatology revenues in 2006 while the international markets will be approximately 25%. We also anticipate that the dermatology sales will continue to increase as a percentage of our overall business to approximate 20% in 2006.

*Gross Profit.* Gross profit was \$18.2 million in 2005, \$14.9 million in 2004 and \$14.1 million in 2003. Gross profit represented 49.1% of sales in 2005, 45.4% of sales in 2004 and 44.4% of sales in 2003. The 3.7% increase in gross profit in 2005 resulted from a 1.9% decrease in direct costs combined with a 1.8% decrease in overhead spending. Additional factors having a positive impact on gross margin include the mix impact of the increase in disposable laser probe revenue and some OEM revenues which may not be repeatable. Overall, we expect gross margins to improve over the next several years.

The 1.0% increase in gross profit in 2004 was due to a 2.0% decrease in overhead spending and a 0.3% increase related to product mix offset by a decrease of 1.2% related to an inventory reserve for saleable, but aging and potentially excess inventory and a decrease of 0.1% associated with average selling prices.

We intend to continue our efforts to reduce the cost of components and thereby mitigate the impact of price reductions on our gross profit. We believe gross profit in dollars will increase as volumes increase and unit production costs will decrease as costs are engineered out of new products. In addition, as we evaluate gross margins on each of our product lines, we may choose to place greater focus on product lines with better margins. Overall, however, gross margins as a percentage of sales will continue to fluctuate due to changes in the relative proportions of domestic and international sales, the product mix of sales, costs associated with future product introductions and a variety of other factors. See "Factors That May Affect Future Results – Our Operating Results May Fluctuate from Quarter to Quarter and Year to Year."

*Research and Development.* Research and development includes the cost of research and product innovation efforts. Research and product innovation expenses decreased by 7.0% in 2005 to \$4.2 million from \$4.5 million in 2004. The decrease in 2005, consisted of a \$0.2 million decrease in project spending and \$0.1 million in decreased clinical spending. The decrease in project spending in 2005 was primarily driven by completion of development of the VariLite and IQ810 lasers in 2004. Research and product innovation expenses increased by 11.8% in 2004 to \$4.5 million from \$4.0 million in 2003. The increase in 2004, consisted of \$0.6 million in increased project spending. These expenses were 11.3% of sales in 2005, 13.7% of sales in 2004 and 12.7% of sales in 2003. The decrease, as a percentage of net sales, from 2004 to 2005 was attributable to the decrease in research and product innovation spending. The increase in research and product innovation expenses in 2004, as a percentage of sales, was due to the increase in expenses in absolute dollars relative to the increase in the level of sales. We expect to continue to

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devote 10% to 12% of our revenues to our research and product innovation efforts for new products and new applications.

*Sales, General and Administrative.* Sales, general and administrative expense increased by 6.3% in 2005 to \$12.2 million from \$11.5 million in 2004. The increase in 2005 was driven by an increase of \$0.3 million in marketing spending, \$0.2 million in increased selling expenses and \$0.2 million in increased general and administrative costs. The increase in marketing spending was primarily related to spending on trade shows, advertising and consulting. The increase in selling expense was due mainly to increased sales headcount and related expenses. General and administrative expense increased primarily due to spending related to the hiring of a new Chief Executive Officer as well as increased consulting, legal expenses and public company expenses offset by a one-time \$1.0 million charge to establish a reserve for unpaid sales tax in 2004. These expenses were 32.9% of sales in 2005, 34.9% of sales in 2004 and 31.8% of sales in 2003. The decrease, as a percentage of net sales, from 2004 to 2005, was attributable to the level of increase in sales, general and administrative expense relative to the increase in the level of sales.

*Interest and Other income, net.* Other income, net consists primarily of interest income earned on available-for-sale securities. Interest income was \$534,000, \$249,000 and \$159,000 in 2005, 2004 and 2003, respectively. Interest income increased in 2005 over 2004 and in 2004 over 2003 based on higher average cash balances and increased interest rates in 2005 and in 2004.

*Income Taxes.* In 2005, our effective rate was 28% and in 2004 it was 47%. In 2003, our effective rate was a benefit of 127%. The tax rate for 2005 was lower than the Federal and State combined statutory rate of 40% because of certain tax benefits associated with tax-exempt interest on tax preferred securities and with tax credits for research and development activities. The tax rates for 2003 resulted primarily due to pretax income approaching breakeven and the level of tax credits for research and development activities relative to the loss for 2003.

## **Liquidity and Capital Resources**

At December 31, 2005, our primary sources of liquidity included cash and cash equivalents of \$12.7 million and available-for-sale securities of \$8.8 million, for a total of \$21.5 million. In addition, we have available \$4.0 million under our unsecured line of credit which bears interest at the bank's prime rate and expires in October 2006. As of December 31, 2005, no borrowings were outstanding under this credit facility. We expect to renew the line of credit in October 2006 assuming that terms continue to be acceptable. We believe that, based on current estimates, our current cash, available-for-sale securities and the credit facility will be sufficient to meet our working capital and capital expenditure requirements at least through the next twelve months. However, we believe that the level of financial resources is a significant competitive factor in our industry, and accordingly we may choose to raise additional capital through debt or equity financing prior to the end of 2006.

Net cash generated by operations in 2005 totaled \$2.8 million. The primary sources of cash in 2005 included net income of \$1.7 million, a decrease in net accounts receivable of \$0.8 million due to a decrease in days sales outstanding and an increase in deferred income taxes of \$0.6 million. Uses of cash in 2005 consisted mainly of a decrease in accrued expenses of \$0.7 million due to payments in 2005 against a sales tax reserve offset by increased bonus accruals for 2005.

Net cash generated by operations in 2004 totaled \$0.8 million and consisted mainly of an increase in net accrued expenses and accounts payable of \$2.0 million due primarily to a reserve for sales tax and associated consulting as well as payroll accruals related to the timing of payroll, depreciation of \$0.4 million, an increase in deferred revenue of \$0.3 million based on increased sales of extended warranty contracts offset by an increase in net accounts receivable of \$0.8 million related mainly to the timing of sales in the fourth quarter of 2004, an increase in the deferred tax asset of \$0.6 million, a net loss of \$0.4 million and an increase in inventory of \$0.2 million associated with inventory purchased in connection with new product introductions.

In 2003 net cash generated by operations was \$5.1 million resulting from decreases in net inventories of \$2.0 million due to an ongoing inventory reduction program, decreases in net accounts receivable of \$1.4 million based on a decrease in days sales outstanding, depreciation of \$0.7 million, an increase in accrued expenses of \$0.6 million due to an increase in income tax payable as well as payroll accruals related to the timing of payroll and net income of \$0.4 million.

We used \$1.5 million, \$2.3 million and \$4.0 million for investing activities in 2005, 2004 and 2003 respectively. Net cash used in investing activities was primarily due to the purchase of available-for-sale securities and the acquisition of fixed assets.

Net cash provided by financing activities during 2005, 2004 and 2003 was \$1.0 million, \$1.4 million and \$0.2 million, respectively, which consisted primarily of issuance of stock in connection with our employee stock programs.

## **Critical Accounting Policies**

The preparation of our condensed consolidated financial statements in conformity with United States Generally Accepted Accounting Principles (GAAP) 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 condensed consolidated financial statements.

### *Revenue Recognition*

Revenue from product sales is recognized upon receipt of a purchase order and product shipment provided 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. Up-front fees received in connection with product sales are deferred and recognized over the associated product shipments. Revenue relating to extended warranty contracts is recognized on a straight line basis over the period of the applicable warranty contract. We recognize service repair revenue upon completion of the work. Cost is recognized as incurred.

### *Warranty*

The Company accrues for estimated warranty costs upon shipment of products in accordance with SFAS No. 5, "Accounting for Contingencies." Actual warranty costs incurred have not materially differed



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from those accrued. The Company's warranty policy is effective for shipped products which are considered defective or fail to meet the product specifications. We analyze failure rates, replacement cost, and design changes when evaluating the adequacy of our warranty reserve. Warranty costs are reflected in the income statement as a cost of revenues. Although we believe we have the ability to reasonably estimate warranty expenses, unforeseen changes in factors affecting the estimate for warranty could occur and such changes could cause a material change in our warranty accrual estimate. Such a change would be recorded in the period in which the charge was identified.

### *Sales Returns Allowance and Allowance for Doubtful Accounts*

In the process of preparing financial statements we must make estimates and assumptions that affect the reported amount of assets and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reported period. Specifically, we must estimate 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 and other allowances. Significant management judgments and estimates must be made and used in connection with establishing the sales returns and other allowances 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. The provision for sales returns amounted to \$0.2 million in 2005. Similarly our management must make estimates of the uncollectibility of our accounts receivable. Management specifically analyzes accounts receivable and analyzes historical bad debts, customer concentrations, customer credit-worthiness and changes in our customer payment terms when evaluating the adequacy of the allowance for doubtful accounts. Our accounts receivable balance was \$6.6 million, net of allowance for doubtful accounts of \$0.6 million as of December 31, 2005.

### *Inventories.*

Inventories are stated at the lower of cost or market and include on-hand inventory, sales demo inventory and service loaner inventory as well as associated inventory reserves. Cost of inventory is determined on a standard cost basis which approximates actual cost on a first-in, first-out (FIFO) method. Adjustments to reduce the cost of inventory to its net realizable value, if required, are made at the product group level for estimated excess, obsolescence or impaired inventory and are charged to cost of goods sold. 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.

### *Income Taxes*

Significant judgment is required in evaluating our tax positions and determining our provision for income taxes. During the ordinary course of business, there are many transactions and calculations for which the ultimate tax determination is uncertain. We establish reserves for tax-related uncertainties based on estimates of whether, and the extent to which, additional taxes and interest will be due. These reserves are established when, despite our belief that our tax return positions are fully supportable, we believe that certain positions are likely to be challenged and may not be sustained on review by tax authorities. We adjust these reserves in light of changing facts and circumstances, such as the closing of a tax audit. The provision for income taxes includes the impact of reserve provisions and changes to reserves that are considered appropriate as well as any related net interest.

### *Deferred Assets and Liabilities*

Deferred assets and liabilities are recognized for the future consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized. Changes in estimate of future levels of taxable income or tax planning strategies could result in the need to provide or increase the valuation allowance against the net deferred tax assets which could materially impact earnings in the period of change.

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### Contractual Obligations

The following table summarizes purchase commitments and minimum rentals due for our facility and other leased assets under long-term, non-cancelable operating leases as of December 31, 2005(in thousands):

	Payments Due by Period					2010 and thereafter
	Total	2006	2007	2008	2009	
Contractual Obligations						
Operating Leases	\$ 1,319	\$ 402	\$ 416	\$ 429	\$ 72	\$ 0
Unconditional Purchase Obligations*	\$ 1,505	\$ 1,505	\$ 0	\$ 0	\$ 0	\$ 0
Total Contractual Cash Obligations	\$ 2,824	\$ 1,907	\$ 416	\$ 429	\$ 72	\$ 0

\*Contractual purchase obligations have varying cancellation terms.

### Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 123R, "*Share-Based Payment — An Amendment of FASB Statements No. 123 and 95*" ("*SFAS 123R*"). The new pronouncement replaces the existing requirements under SFAS 123 and APB 25. According to SFAS 123R, all forms of share-based payments to employees, including employee stock options and employee stock purchase plans, would be treated the same as any other form of compensation by recognizing the related cost in the statement of operations. This pronouncement eliminates the ability to account for stock-based compensation transactions using APB 25 and generally requires that such transactions be accounted for using a fair-value based method. The statement requires companies to assess the most appropriate model to calculate the value of the options. We currently use the Black-Scholes option pricing model to value options; however, we are currently assessing which model we may use in the future under the new statement and may deem an alternative model to be the most appropriate. The use of a different model to value options may result in a different fair value than would result from the use of the Black-Scholes option pricing model. In addition, there are a number of other requirements under the new standard that would result in different accounting treatment than is currently required. These differences include, but are not limited to, the accounting for the tax benefit on employee stock options and for stock issued under our employee stock purchase plan, and the presentation of these tax benefits within the statement of cash flows. We will adopt SFAS 123R using the prospective method of adoption.

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In March 2005, the SEC issued Staff Accounting Bulletin No. 107, “*Share-Based Payment*” (“SAB 107”). SAB 107 provides guidance on the initial implementation of SFAS 123R. In particular, the statement includes guidance related to share-based payment awards for non-employees, valuation methods and selecting underlying assumptions such as expected volatility and expected term. SAB 107 also gives guidance on the classification of compensation expense associated with such awards and accounting for the income tax effects of those awards upon the adoption of SFAS 123R.

In April 2005, the SEC announced the adoption of a new rule that amends the effective date of SFAS 123R. The effective date of the new standard under these new rules for our financial statements is January 1, 2006. Adoption of this statement is expected to have a significant impact on our financial statements as we will be required to expense the fair value of our stock option grants and stock purchases under our employee stock purchase plan (“ESPP”) rather than disclose the impact on our net loss within our footnotes, as is our current practice. The full impact of SFAS 123R on our financial statements and related disclosures is still being evaluated by management but is expected to be material to our results of operations. Our actual share-based compensation expense in 2006 will be dependent on a number of factors, including the amount of awards granted and the fair value of those awards at the time of grant.

In May 2005, the FASB issued SFAS No. 154, “*Accounting Changes and Error Corrections - replacement of APB Opinion No. 20 and FASB Statement No. 3*” (“SFAS 154”). SFAS 154 changes the accounting for and reporting of a change in accounting principle by requiring retrospective application to prior periods’ financial statements of changes in accounting principle unless impracticable. SFAS 154 is effective for accounting changes made in fiscal years beginning after December 15, 2005. We do not expect the adoption of SFAS 154 to have a material impact on our results of operations, financial position or cash flows.

### **Factors That May Affect Future Results**

In addition to the other information contained in this Form 10-K, we have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operation. You should carefully consider the risks described below before making an investment decision.

*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 light therapeutic-based photocoagulator medical laser systems and delivery devices to the ophthalmology and dermatology 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;
- § Acceptance of the company’s new marketing programs;
- § Recommendations and opinions by ophthalmologists, dermatologists, other clinicians, plastic surgeons and their associated opinion leaders, including study outcomes;
- § Price of our products and prices of competing products and technologies;
- § Availability of competing products, technologies and alternative treatments; and
- § Level of reimbursement for treatments administered with our products.

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In addition, we derive a meaningful portion of our sales from recurring revenues including disposable laser probes, EndoProbes and service. Our ability to increase recurring revenues from the sale of EndoProbes will depend primarily upon the features and product innovation, ease of use and prices of our products, including the relationship to prices of competing delivery devices. The level of service revenues will depend on our quality of care, 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 or services would have a material adverse effect on our business, results of operations and financial condition.

*We Face Strong Competition in Our Markets and Expect the Level of Competition to Grow in the Foreseeable Future.* Competition in the market for devices used for ophthalmic and dermatology 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 Lumenis Ltd., Nidek, Carl Zeiss, Inc., Alcon, and Synergetics, Inc. All of these companies currently offer a competitive semiconductor-based laser system in ophthalmology. Also within ophthalmology pharmaceutical alternative treatments for AMD such as Visudyne (Novartis) , Macugen (Eyeteck) and Lucentis (Genentech) compete rigorously with traditional laser procedures. Our principal competitors in dermatology are Palomar Technologies, Candela Corporation, Syneron, Lumenis Ltd. and Laserscope. Some competitors have substantially greater financial, engineering, product development, manufacturing, marketing and technical resources than we do. Some companies also have greater name recognition than we do and long-standing customer relationships. In addition to other companies that manufacture photocoagulators, we compete with pharmaceuticals, other technologies and other surgical techniques. 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 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,

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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 United States Food and Drug Administration, or 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.

*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.* We have experienced declines in the average unit price of our products and expect to continue to suffer from declines in the future. 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.

*We Depend on Sales of Our Ophthalmology Products for a Significant Portion of Our Operating Results.* We derive, and expect to continue to derive, a large portion of our revenue and profits from sales of our ophthalmology products. In 2005, 2004 and 2003 sales of our ophthalmology products were \$30.7 million, \$27.8 million and \$26.2 million or 82.8%, 84.6% and 82.5%, respectively, of total sales. We anticipate that sales of our ophthalmology products will continue to account for a significant portion of our revenues in the foreseeable future.

*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 revenue from international sales. In 2005, 2004 and 2003, our international sales were \$14.3 million, \$12.9 million and \$11.6 million or 38.7%, 39.4% and 36.7%, respectively, 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. 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 including:

- § Impact of recessions in economies outside of the United States;
- § Performance of our international channel of distributors;
- § Foreign certification requirements, including continued ability to use the “CE” mark in Europe;

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- § Reduced or limited protections of intellectual property rights in jurisdictions outside the United States;
- § Longer accounts receivable collection periods;
- § 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. For additional discussion about our foreign currency risks, see Item 3, “Quantitative and Qualitative Disclosures about Market Risk.”

*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 revenue 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 18 employees and we maintain relationships with 77 independent distributors internationally selling our products into 107 countries through four direct Area Sales Managers. 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 or fails to generate sales of our products, we may be forced to replace the distributor and our ability to sell our products into that exclusive sales territory would be adversely affected.

We do not have any long-term employment contracts with the members of our direct sales force. We may be unable to replace our direct sales force personnel with individuals of equivalent technical expertise and qualifications, which may 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 distributorship 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.

*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.

*We Face Manufacturing Risks.* The manufacture of our infrared and visible light photocoagulators and the related delivery devices (including EndoProbes) is a highly complex and precise process. We assemble critical subassemblies and 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. 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 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

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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. Over the past several quarters, we have placed a high priority on our asset management efforts to, among other things, reduce overall inventory levels and increase our cash position. If we underestimate demand for our product and, consequently, our component and materials requirements, we may have inadequate inventory, which could interrupt our manufacturing, delay delivery of our product to our customers and result in the loss of customer sales. Any of these occurrences would negatively impact our business and operating results.

*We Depend on Sole Source or Limited Source Suppliers.* We rely on third parties to manufacture substantially all of the components used in our products, including optics, laser diodes and crystals. We have some long term or volume purchase agreements with our suppliers and currently purchase components on a purchase order basis. Some of our suppliers and manufacturers are sole or limited sources. In addition, some of these suppliers are relatively small private companies 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. We do not currently intend to manufacture any of these components. 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.

*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;

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- Changes in demand for our existing line of dermatology and ophthalmic products;
- The cost and availability of components and subassemblies, including the ability of our sole or limited source suppliers to 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 dermatology and ophthalmic products and foreign and domestic sales;
- The effect of regulatory approvals and changes in domestic and foreign regulatory requirements;
- Introduction of new products, product enhancements and new applications by our competitors, 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;
- 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.

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. From time to time, we meet with investors and potential investors. In addition, we receive attention by securities analysts and present at analyst meetings when invited. Our common stock may experience an imbalance between supply and demand resulting from low trading volumes. In addition, the stock market has experienced extreme volatility in the last few years that has often been unrelated to the performance of particular companies. These broad market fluctuations could have a significant impact on the market price of our common stock regardless of our performance.

*We Are Subject To Government Regulation 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 (PMA) 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.

*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 (532 nm) laser photocoagulator module, 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. We cannot assure you that our relationship with



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Bausch & Lomb will result in further sales of our Millennium Endolase module. 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.

*We Face Risks Associated with our Collaborative and OEM Relationships.* Our collaborators may not pursue further development and commercialization of products resulting from collaborations with us or may not devote sufficient resources to the marketing and sale of such products. For example, in 2005 we developed and sold a laser system on an OEM basis for a third party which positively impacted the gross margins during the third quarter. We cannot be assured that these types of relationships will continue over a longer period. Our reliance on others for clinical development, manufacturing and distribution of our products may result in unforeseen problems. Further, our collaborative partners may develop or pursue alternative technologies either on their own or in collaboration with others. If a collaborator elects to terminate its agreement with us, our ability to develop, introduce, market and sell the product may be significantly impaired and we may be forced to discontinue altogether the product resulting from the collaboration. We may not be able to negotiate alternative collaboration agreements on acceptable terms, if at all. The failure of any current or future collaboration efforts 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.

*We are Dependent on the Successful Outcome of Clinical Trials of Our Products and New Applications Using Our Products.* Our success will depend in part on the successful outcome of clinical trials of our products and new applications using our products. Clinical trials are long, expensive and uncertain processes. If the future results of any clinical trial regarding our products fails to demonstrate improved outcomes of treatment using our products, our ability to generate revenues from new products or new applications using our products would be adversely affected. We have supported several clinical trials, including, for example, the TTT4CNV and the PTAMD clinical trials.

The TTT4CNV clinical trial was a physician initiated multi-center, prospective, double-masked, placebo-controlled, randomized trial conducted at 22 centers in the United States conducted to determine whether TTT laser treatment using our OcuLight SLx infrared laser system and Large Spot Slit Lamp Adapter can reduce the risk of vision loss for patients with wet age-related macular degeneration (“wet AMD”) compared to a randomized control. In October 2004, we announced that the preliminary visual outcome data in the intent-to-treat evaluation showed that TTT, as applied in the TTT4CNV trial, showed favorable trends but overall did not demonstrate a significant beneficial effect relative to sham treatments and announced that further subgroup analysis would be conducted. Since that time, results of subgroup analysis have demonstrated a statistically significant benefit in a subgroup of patients with baseline visual acuity of 20/100 or worse. Within the TTT4CNV Clinical trial, about 41% of the patients enrolled had baseline vision of 20/100 or worse. Specifically, at 12 months following treatment 23% of TTT treated eyes improved vision by one or more lines and 14% of TTT treated eyes improved vision by three or more lines compared with none of the eyes in the placebo treated control group. Furthermore, at 18 months, there was a 2 line benefit in preserving vision in this subgroup when compared to placebo treated eyes. Specifically, TTT treated eyes on average lost 2 lines of visual acuity while placebo treated eyes lost 4 lines. Comparing these results to alternative therapies, it is not clear where TTT will eventually fit into the treatment regimen of wet AMD, therefore any impact on laser sales related to these trial results may take a number of years.

The PTAMD clinical trial was a physician initiated multi-center, prospective, randomized trial conducted at 21 centers in the North America conducted to determine whether a MIP laser treatment using our OcuLight SLx infrared laser system and Slit Lamp Adapter could (1) Provide a prophylactic benefit from a single subthreshold laser treatment in slowing the progression of AMD from dry (drusen) to wet (CNV); and (2) Was there a therapeutic benefit from a single subthreshold laser treatment in drusen reduction and vision in these eyes compared to a randomized control. Eligible patients with dry AMD were enrolled into one of two arms. Patients with dry AMD in one eye and wet AMD in the other eye were placed in one arm (The Unilateral study arm), while patients with dry AMD in both eyes were placed in the second arm (The Bilateral study arm). In April 2000, we announced that enrollment of patients into the Unilateral study arm was stopped at 243 patients as results showed that: (1) Treatment did not reduce the incidence of choroidal neovascularization and, in fact, was associated with a significantly higher incidence of CNV compared to observed eyes; and (2) Treatment did not improve visual acuity. In October 2005, initial results from the PTAMD Bilateral study arm were presented. A total of 1278 eyes were enrolled in the Bilateral study arm and followed for up to 5 years. Results showed that: (1) There was no beneficial prophylactic treatment effect on CNV occurrence; and there was no trend toward a beneficial effect; and (2) The study did show a therapeutic benefit in drusen reduction and vision in treated eyes. Drusen significantly reduced after a single sub-threshold infrared laser treatment at 12 months and at 24 months ( $P < 0.0001$ ). In all eyes enrolled visual acuity changes showed some indication of a beneficial effect of treatment at 18 months and onward. At month 24 treated eyes showed a 1.5 letter beneficial difference in VA compared to the observed eye ( $P = 0.04$ ); Treated eyes also had a higher percentage (12% vs. 8%) showing a 2 or more line gain. In a sub-group of eyes with 20/30 or worse baseline VA the beneficial effect of treatment was more pronounced. At month 24 treated eyes showed a 4.0 letter (~1 line) beneficial difference in VA with treated eyes improving 2.9 letters and observed eyes losing 1.1 letters ( $P = 0.0034$ ). Treated eyes had a higher percentage (31% vs. 19%) showing a 2 or more line gain, and a lower percentage (13% vs. 22%) showing a 2 or more line loss. Additional results will be presented during 2006. It is still too early to determine the eventual position of laser treatment of drusen in the overall treatment regimen of dry AMD, therefore any impact on laser sales related to these trial results may take a number of years.

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*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 we modify one of our FDA approved or cleared devices, we may need to seek new approvals or clearances which, if not granted, would prevent us from selling our modified products.

Any modifications to an FDA-approved or 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 PMA approval. We may not be able to obtain additional 510(k) clearances or PMA approvals for new products or for modifications to, or additional intended uses or 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 revenue and future profitability. We have made modifications to our devices and the labeling of 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 stop marketing the modified devices, which could harm our operating results and require us to redesign or relabel our products.

*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 fifteen United States patents and five foreign patents on the technologies related to our products and processes. We have approximately five pending patent applications in the United States and five foreign pending patent applications that have been filed. Our patent applications may not be approved. Any patents granted now or in the future may offer only limited protection against potential infringement and development by our competitors of competing products. Moreover, our competitors, many of which have substantial resources and have made substantial investments in competing technologies, may seek to apply for and obtain patents that will prevent, limit or interfere with our ability to make, use or sell our products either in the United States or in international markets.

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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 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. Until recently patent applications were maintained in secrecy in the United States until the patents issued. 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 noninfringing technology or to enter into royalty or licensing agreements. An adverse determination in a judicial or administrative proceeding and failure to obtain necessary licenses or develop alternate technologies could prevent us from manufacturing and selling our products, which would have a material adverse effect on our business, results of operations and financial condition. In October 2005, the Company filed suit against Synergetics, USA, Inc. for infringement of a patent. The Company seeks injunctive relief, monetary damages, treble damages, cost and attorneys' fees. Synergetics answered the Company's complaint in November 2005 and denied liability for patent infringement, filing counterclaims seeking a declaratory judgment that it did not infringe the Company's patent. Synergetics also brought three additional counterclaims for false advertising, commercial disparagement, trade libel, injurious falsehood, unfair competition, disparagement of property, slander of goods and defamation, under state and federal law, based upon allegations that the Company had raised safety issues involving Synergetics' product with the Food and Drug Administration and the public. Synergetics seeks monetary damages, costs and attorneys' fees. While we believe its not material to the Company's operation, the company may incur significant dedication of management resources and legal costs in connection with this lawsuit.

*The Requirements of Complying with the Sarbanes-Oxley Act of 2002 Might Strain Our Resources, Which May Adversely Affect Our Business and Financial Condition.* We are subject to a number of requirements, including the reporting requirements of the Securities Exchange Act of 1934, as amended, and the Sarbanes-Oxley Act of 2002. These requirements might place a strain on our systems and resources. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, significant resources and management oversight will be required. As a result, our management's attention might be diverted from other business concerns, which could have a material adverse effect on our business, financial condition, and operating results. In addition, we might need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge, and we might not be able to do so in a timely fashion.

*Our Operating Results May be Adversely Affected by Changes in Third Party Coverage and Reimbursement Policies and any Uncertainty Regarding Healthcare Reform Measures.* 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

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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. In addition, third party payers may not initiate coverage of new procedures using our products for a significant period. In September 2000, the Center for Medicare and Medicaid Services, or CMS, advised that claims for reimbursement for certain age related macular degeneration, or AMD, procedures which use our OcuLight SLx laser system, could be submitted for reimbursement, with coverage and payment to be determined by the local medical carriers at their discretion. To date five carriers representing 17 states have written reimbursement coverage policies on Transpupillary Thermotherapy, or TTT. The states reimbursing for TTT are Alaska, Arizona, California, Colorado, Hawaii, Iowa, Idaho, Mississippi, North Carolina, North Dakota, Nevada, Oregon, Pennsylvania, South Dakota, Tennessee, Washington and Wyoming. Domestic sales of the OcuLight SLx laser system may continue to be limited until more local medical carriers reimburse for performing such AMD procedures or until CMS advises that claims for these procedures may be submitted directly to CMS at the national level. The clinical results of the TTT4CNV trial and other clinical trials may influence the individual state or CMS decision to reimburse for certain laser procedures. In November 2005, IRIDEX filed a CPT (Current Procedural Terminology) Change Request Form seeking the extension of Category III (Emerging Technology) codes 0016T and 0017T for wet and dry forms of AMD.

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.

*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 and skin conditions on and near a patient's face. Although we maintain product liability insurance with coverage limits of \$10.0 million per occurrence and an annual aggregate maximum of \$10.0 million, our coverage from our insurance policies may not be adequate. Product liability insurance is expensive. 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.

*If We Fail to Manage Growth Effectively, Our Business Could Be Disrupted Which Could Harm Our Operating Results.* We have experienced and may continue to experience growth in our business. 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.

*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

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product innovation 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 May Need Additional Capital, which May Not Be Available, and Our Ability to Grow May be Limited as a Result.* We believe that our existing cash balances, available-for-sale securities, credit facilities and cash flow expected to be generated from future operations will be sufficient to meet our capital requirements at least through the next 12 months. However, we may be required, or could elect, to seek additional funding prior to that time. The development and marketing of new products and associated support personnel requires a significant commitment of resources. If cash from available sources is insufficient, we may need additional capital, which may not be available on favorable terms, if at all. If we cannot raise funds on acceptable terms, we may not be able to develop or enhance our products, take advantage of future opportunities, fund potential acquisitions or respond to competitive pressures or unanticipated requirements. Any inability to raise additional capital when we require it would seriously harm our business.

*Failure to Remediate the Material Weaknesses in Our Disclosure Controls and Procedures in a Timely Manner, or At All, Could Harm Our Operating Results or Cause Us to Fail to Meet Our Regulatory or Reporting Obligations.* We evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report and, based on this evaluation, management concluded that as of December 31, 2005, our disclosure controls and procedures were not effective because of the material weaknesses detailed in Item 9A, Part II (Controls and Procedures) of this report. In particular, the material weakness was identified related to a failure to maintain adequate period-end review procedures over general ledger accounts. As a result, an error in a system generated custom inventory report and errors in two key spreadsheets related to warranty and deferred revenue resulted in incorrect entries being recorded to the financial statements which were not identified and corrected by management in a timely manner. While we believe that the material weaknesses did not have a material effect on our reported results, they nevertheless constituted deficiencies in our disclosure controls and procedures. In addition, to remediate the material weaknesses summarized above, we may need to implement additional controls over the preparation and review of key spreadsheets, implement automated general ledger reports to replace existing key spreadsheets where possible, correct a system generated custom report to include additional information necessary to prepare accurate financial information, implement additional review procedures and enhance the current capabilities of the finance function. If, despite our remediation efforts, we fail to ameliorate our material weaknesses, we could be subject to regulatory scrutiny and a loss of public confidence in our disclosure controls and procedures. These remediation efforts will likely increase our general and administrative expenses and could, therefore, have an adverse effect on our reported net income.

Even if we are to successfully remediate such material weaknesses, because of its inherent limitations, our disclosure controls and procedures may not prevent or detect misstatements or material omissions. 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.

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

### **Quantitative Disclosures**

We are exposed to market risks inherent in our operations, primarily related to interest rate risk and currency risk. These risks arise from transactions and operations entered into in the normal course of business. We do not use derivatives to alter the interest characteristics of our marketable securities or our debt instruments. We have no holdings of derivative or commodity instruments.

*Interest Rate Risk.* We are subject to interest rate risks on cash and cash equivalents, available-for-sale marketable securities and any future financing requirements. Interest rate risks related to marketable securities are managed by managing maturities in our marketable securities portfolio. As of December 31, 2005, our available-for-sale marketable securities have an average of 50 days to maturity. We have no long-term debt as of December 31, 2005.

The fair value of our investment portfolio or related income would not be significantly impacted by changes in interest rates since the marketable securities maturities do not extend beyond fiscal year 2006 and the interest rates are primarily fixed.

### **Qualitative Disclosures**

*Interest Rate Risk.* Our primary interest rate risk exposures relate to:

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- The available-for-sale securities will fall in value if market interest rates increase.
- The impact of interest rate movements on our ability to obtain adequate financing to fund future operations.

We have the ability to hold at least a portion of the fixed income investments until maturity and therefore would not expect the operating results or cash flows to be affected to any significant degree by a sudden change in market interest rates on our short and long-term marketable securities portfolio.

Management evaluates its financial position on an ongoing basis.

### *Currency Rate Risk.*

We do not hedge any balance sheet exposures against future movements in foreign exchange rates. The exposure related to currency rate movements would not have a material impact on future net income or cash flows.

## **Item 8. Financial Statements and Supplementary Data**

Our consolidated balance sheets as of December 31, 2005 and January 1, 2005 and the consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the three years in the period ended December 31, 2005, 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 14.

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of IRIDEX Corporation:

In our opinion, the consolidated financial statements listed in the index appearing under Item 15(a)(1) present fairly, in all material respects, the financial position of IRIDEX Corporation and its subsidiaries at December 31, 2005 and January 1, 2005, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2005 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the index appearing under Item 15(a)(2) presents fairly in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements 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. An audit 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, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

San Jose, California  
March 31, 2006

**IRIDEX Corporation**  
**CONSOLIDATED BALANCE SHEETS**  
**(in thousands, except share and per share data)**

	December 31, 2005	January 1, 2005
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 12,655	\$ 10,381
Available-for-sale securities	8,779	3,323
Accounts receivable, net of allowance for doubtful accounts of \$559 in 2005 and \$466 in 2004	6,589	7,404
Inventories, net	8,594	8,922
Prepays and other current assets	885	814
Short term deferred income taxes	1,415	1,808
Total current assets	<u>38,917</u>	<u>32,652</u>
Long term portion of available-for-sale securities	—	4,324
Property and equipment, net	1,114	852
Deferred income taxes	1,073	1,265
Total assets	<u>\$ 41,104</u>	<u>\$ 39,093</u>

**LIABILITIES AND STOCKHOLDERS' EQUITY**

Current liabilities:		
Accounts payable	\$ 1,094	\$ 1,233
Accrued expenses	4,421	5,167
Deferred revenue	1,072	910
Total liabilities	<u>6,587</u>	<u>7,310</u>

Commitments and contingencies (Note 5).

Stockholders' Equity		
Convertible Preferred Stock, \$.01 par value:		
Authorized: 2,000,000 shares;		
Issued and outstanding: none	—	—
Common Stock, \$.01 par value:		
Authorized: 30,000,000 shares;		
Issued and outstanding: 7,520,358 shares in 2005 and 7,308,857 shares in 2004	76	74
Additional paid-in capital	26,334	25,281
Accumulated other comprehensive loss	(27)	(35)
Treasury stock, at cost	(430)	(430)
Retained earnings	8,564	6,893
Total stockholders' equity	<u>34,517</u>	<u>31,783</u>
Total liabilities and stockholders' equity	<u>\$ 41,104</u>	<u>\$ 39,093</u>

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



**IRIDEX Corporation**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
(in thousands, except per share data)

	Year Ended December 31, 2005	Year Ended January 1, 2005	Year Ended January 3, 2004
Sales	\$ 37,029	\$ 32,810	\$ 31,699
Cost of sales	18,854	17,922	17,628
Gross profit	<u>18,175</u>	<u>14,888</u>	<u>14,071</u>
Operating expenses:			
Research and development	4,195	4,509	4,032
Sales, general and administrative	12,171	11,455	10,087
Total operating expenses	<u>16,366</u>	<u>15,964</u>	<u>14,119</u>
Income (loss) from operations	1,809	(1,076)	(48)
Interest and other income, net	528	319	212
Income (loss) before income taxes	2,337	(757)	164
Benefit from (provision for) income taxes	(666)	355	207
Net income (loss)	<u>\$ 1,671</u>	<u>\$ (402)</u>	<u>\$ 371</u>
Basic net income (loss) per common share	<u>\$ 0.23</u>	<u>\$ (0.06)</u>	<u>\$ 0.05</u>
Diluted net income (loss) per common share	<u>\$ 0.21</u>	<u>\$ (0.06)</u>	<u>\$ 0.05</u>
Shares used in net income (loss) per common share basic calculations	<u>7,405</u>	<u>7,200</u>	<u>6,933</u>
Shares used in net income (loss) per common share diluted calculations	<u>7,880</u>	<u>7,200</u>	<u>7,072</u>

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

**IRIDEX Corporation**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Treasury Stock	Accumulated Other Comprehensive Income (Loss)	Retained Earnings	Total
	Shares	Amount					
Balances, December 28, 2002	6,905,998	\$ 70	\$ 23,631	\$ (430)	\$ 3	\$ 6,924	\$ 30,198
Issuance of Common Stock under Stock Option Plan	52,466		179				179
Issuance of Common Stock under Employee Stock Purchase Plan	28,569		75				75
Tax Benefit of Employee Stock Option Plan			15				15
Change in unrealized gains on available-for-sale securities					(4)		(4)
Net income						371	371
Balances, January 3, 2004	6,987,033	70	23,900	(430)	(1)	7,295	30,834
Issuance of Common Stock under Stock Option Plan	294,852	4	1,081				1,085
Issuance of Common Stock under Employee Stock Purchase Plan	26,972		122				122
Tax Benefit of Employee Stock Option Plan			178				178
Change in unrealized gains on available-for-sale securities					(34)		(34)
Net loss						(402)	(402)
Balances, January 1, 2005	7,308,857	74	25,281	(430)	(35)	6,893	31,783
Issuance of Common Stock under Stock Option Plan	183,873	2	661				663
Issuance of Common Stock under Employee Stock Purchase Plan	27,628		134				134
Tax Benefit of Employee Stock Option Plan			171				171
Change in unrealized gains on available-for-sale securities					8		8
Warrants issued for services			87				87
Net income						1,671	1,671
Balances, December 31, 2005	<u>7,520,358</u>	<u>\$ 76</u>	<u>\$ 26,334</u>	<u>\$ (430)</u>	<u>\$ (27)</u>	<u>\$ 8,564</u>	<u>\$ 34,517</u>

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

**IRIDEX Corporation**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(in thousands)**

	Year Ended December 31, 2005	Year Ended January 1, 2005	Year Ended January 3, 2004
<b>Cash flows from operating activities:</b>			
Net income (loss)	\$ 1,671	\$ (402)	\$ 371
<b>Adjustments to reconcile net income (loss) to net cash provided by operating activities:</b>			
Depreciation and amortization	435	384	703
Issuance of warrant	87	—	—
Provision for doubtful accounts	132	376	(142)
Provision for inventories	407	694	(63)
Deferred income taxes	585	(579)	(235)
<b>Changes in assets and liabilities:</b>			
Accounts receivable	683	(1,232)	1,631
Inventories	(436)	(895)	2,067
Prepays and other current assets	(71)	120	(175)
Accounts payable	(139)	204	372
Accrued expenses	(746)	1,787	356
Deferred revenue	162	314	203
Net cash provided by operating activities	<u>2,770</u>	<u>771</u>	<u>5,088</u>
<b>Cash flows from investing activities:</b>			
Purchases of available-for-sale securities	(8,770)	(7,681)	(5,755)
Proceeds from maturity of available-for-sale securities	7,646	5,751	2,356
Acquisition of property and equipment	(340)	(386)	(603)
Net cash used in investing activities	<u>(1,464)</u>	<u>(2,316)</u>	<u>(4,002)</u>
<b>Cash flows from financing activities:</b>			
Issuance of common stock under stock purchase and option plans	968	1,385	269
Net cash provided by financing activities	<u>968</u>	<u>1,385</u>	<u>269</u>
Net increase (decrease) in cash and cash equivalents	2,274	(160)	1,355
Cash and cash equivalents, beginning of year	<u>10,381</u>	<u>10,541</u>	<u>9,186</u>
Cash and cash equivalents, end of year	<u>\$ 12,655</u>	<u>\$ 10,381</u>	<u>\$ 10,541</u>
<b>Supplemental disclosure of cash flow information:</b>			
<b>Cash paid during the year for:</b>			
Income taxes	\$ 209	\$ 25	\$ 138

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

**IRIDEX Corporation**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)**  
**(in thousands)**

	Year Ended December 31, 2005	Year Ended January 1, 2005	Year Ended January 3, 2004
Net income (loss)	\$ 1,671	\$ (402)	\$ 371
Other comprehensive loss:			
Changes in unrealized losses on available-for-sale securities, net	<u>6</u>	<u>(34)</u>	<u>(4)</u>
Comprehensive income (loss)	<u>\$ 1,677</u>	<u>\$ (436)</u>	<u>\$ 367</u>

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

**IRIDEX Corporation**  
**Notes to Consolidated Financial Statements**

**1. Business of the Company**

*Description of Business*

IRIDEX Corporation is a worldwide provider of therapeutic based laser systems used to treat eye diseases in ophthalmology and skin lesions in dermatology.

**2. Summary of Significant Accounting Policies**

*Financial Statement Presentation*

The consolidated financial statements include our accounts and our wholly-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated.

*Cash and Cash Equivalents*

The Company considers all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents. The Company invests primarily in money market funds and government paper; accordingly, these investments are subject to minimal credit risk.

*Available-for-Sale Securities*

All marketable securities as of December 31, 2005 and January 1, 2005 are considered to be available-for-sale and therefore are carried at fair value. Available-for-sale securities are classified as current assets when they have scheduled maturities of less than one year. Available-for-sale securities are classified as non current assets when they have scheduled maturities of more than one year. Marketable securities include auction rate and floating rate securities. These securities are structured as short-term, highly liquid investments that can be readily converted into cash every 30, 60 or 90 days. However, since the stated or contractual maturities of these securities is greater than 90 days, these securities are classified as marketable securities and not cash equivalents. Unrealized holding gains and losses on such securities are reported net of related taxes as a separate component of stockholders' equity until realized. Realized gains and losses on sales of all such securities are reported in interest and other income and are computed using the specific identification cost method.

*Sales Returns Allowance and Allowance for Doubtful Accounts*

In the process of preparing financial statements we must make estimates and assumptions that affect the reported amount of assets and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reported period. Specifically, we must estimate 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 and other allowances. Significant management judgments and estimates must be made and used in connection with establishing the sales returns and other allowances 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. The provision for sales returns amounted to \$0.2 million in 2005, 2004 and 2003. Similarly our management must make estimates of the uncollectibility of our accounts receivable. Management specifically analyzes accounts receivable and

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analyzes historical bad debts, customer concentrations, customer credit-worthiness, current economic trends and changes in our customer payment terms when evaluating the adequacy of the allowance for doubtful accounts.

### *Inventories*

Inventories are stated at the lower of cost or market and include on-hand inventory, sales demo inventory and service loaner inventory. Cost is determined on a standard cost basis which approximates actual cost on a first-in, first-out (FIFO) method. Lower of cost or market is evaluated by considering obsolescence, excessive levels of inventory, deterioration and other factors. Adjustments to reduce the cost of inventory to its net realizable value, if required, are made for estimated excess, obsolescence or impaired inventory and are charged to cost of goods sold. 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.

### *Property and Equipment*

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is provided on a straight-line basis over the estimated useful lives of the assets, which is generally three years. Amortization of leasehold improvements and property and equipment is computed using the straight-line method over the estimated useful life of the related assets, typically three years.

### *Revenue Recognition*

Revenue from product sales is recognized upon receipt of a purchase order and product shipment provided 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. Up-front fees received in connection with product sales are deferred and recognized over the associated product shipments. Revenue relating to extended warranty contracts is recognized on a straight line basis over the period of the applicable warranty contract. We recognize service repair revenue upon completion of the work. Cost is recognized as incurred.

### *Deferred Revenue*

Revenue related to warranty contracts is recognized on a straight line basis over the period of the applicable contract. Cost is recognized as incurred. A reconciliation of the changes in the Company's deferred revenue balances for the years ended January 1, 2005 and December 31, 2005 follows (in thousands):

Balance, January 3, 2004	\$ 596
Additions to deferral	1,146
Revenue recognized	<u>(832)</u>
Balance, January 1, 2005	910
Additions to deferral	1,451
Revenue recognized	<u>(1,289)</u>
Balance, December 31, 2005	<u>\$ 1,072</u>

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### *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 effective for shipped products which are considered defective or fail to meet the product specifications. Warranty costs are reflected in the statement of operations as a cost of sales. A reconciliation of the changes in the Company's warranty liability for the years ended January 1, 2005 and December 31, 2005 follows (in thousands):

Balance, January 3, 2004	\$ 801
Accruals for warranties issued during the year	861
Settlements made in kind during the year	<u>(729)</u>
Balance, January 1, 2005	\$ 933
Accruals for warranties issued during the year	1,163
Settlements made in kind during the year	<u>(968)</u>
Balance, December 31, 2005	<u>\$ 1,128</u>

### *Research and Development*

Research and development expenditures are charged to operations as incurred.

### *Advertising*

We expense advertising costs as they are incurred. Advertising expenses for 2005, 2004 and 2003 were \$288,000, \$218,000 and \$311,000, respectively.

### *Fair Value of Financial Instruments*

Carrying amounts of our financial instruments including cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate fair value due to their short maturities.

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Estimated fair values for available-for-sale securities, which are separately disclosed elsewhere, are based on quoted market prices for the same or similar instruments.

### *Income Taxes*

Deferred assets and liabilities are recognized for the future consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

### *Accounting for Stock-Based Compensation*

The Company accounts for stock-based compensation arrangements in accordance with provisions of Accounting Principles Board Opinion (“APB”) No. 25, “Accounting for Stock Issued to Employees”) and complies with the disclosure provisions of Statement of Financial Accounting Standards No. 123, “Accounting for Stock-Based Compensation” (“SFAS 123”) as amended by SFAS No. 148, Accounting for Stock-Based Compensation – Transition and Disclosure – an amendment of FASB Statement No. 123.

Under APB 25, compensation expense for grants to employees is based on the difference, if any, on the date of the grant, between the fair value of the Company’s stock and the option’s exercise price. SFAS 123 defines a “fair value” based method of accounting for an employee stock option or similar equity investment. The pro forma disclosure of the difference between compensation expense included in net loss and the related cost measured by the fair value method is presented below.

The following table provides a reconciliation of net income (loss) to pro forma net loss as if the fair value method had been applied to all awards (in thousands, except per share data):

	<u>Year Ended December 31, 2005</u>	<u>Year Ended January 1, 2005</u>	<u>Year Ended January 3, 2004</u>
Net income (loss), as reported	\$ 1,671	\$ (402)	\$ 371
Add: Total stock based compensation expense determined under fair value based method for all awards, net of tax	<u>(966)</u>	<u>(560)</u>	<u>(534)</u>
Pro forma net income (loss)	<u>\$ 705</u>	<u>\$ (962)</u>	<u>\$ (163)</u>
Basic net income (loss) per share:			
As reported	<u>\$ 0.23</u>	<u>\$ (0.06)</u>	<u>\$ 0.05</u>
Pro forma	<u>\$ 0.10</u>	<u>\$ (0.13)</u>	<u>\$ (0.02)</u>
Diluted net income (loss) per share:			
As reported	<u>\$ 0.21</u>	<u>\$ (0.06)</u>	<u>\$ 0.05</u>
Pro forma	<u>\$ 0.09</u>	<u>\$ (0.13)</u>	<u>\$ (0.02)</u>



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The fair value of each option grant has been estimated on the date of grant using the Black-Scholes multiple option pricing model with the following weighted average assumptions:

	2005		2004		2003	
	Group A	Group B	Group A	Group B	Group A	Group B
Risk-free Interest Rates	4.40%	4.40%	3.50%	3.50%	3.30%	3.30%
Expected Life	7 years	5 years	4 years	4 years	4 years	4 years
Volatility	0.83	0.77	0.88	0.88	0.88	0.88
Dividend Yield	—	—	—	—	—	—

The weighted average expected life was calculated based on the exercise behavior of each group. Group A represents officers and directors who are a smaller group holding a greater average number of options than other option holders and who tend to exercise later in the vesting period. Group B are all other option holders, virtually all of whom are employees. This group tends to exercise earlier in the vesting period.

The weighted average grant-date fair value per share of those options granted in 2005, 2004 and 2003 was \$4.45, \$4.89 and \$2.96, respectively.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS 123 and Emerging Issues Task Force Issue No. 96-18, "Accounting for Equity Instruments that are Issued to Other Than Employees, or in Conjunction with Selling Goods and Services," as amended by SFAS No. 148, "Accounting for Stock-Based Compensation – Transition and Disclosure – an Amendment of FASB Statement No. 123." Stock-based compensation expense related to stock options granted to non-employees is recognized on a straight line basis as the stock options are earned. The stock-based compensation expense will fluctuate as the deemed fair market value of the common stock fluctuates. There were no equity instruments issued to non-employees in 2005, 2004 and 2003.

The Company has also estimated the fair value for the purchase rights issued under our 1995 Employee Stock Purchase Plan, under the Black-Scholes valuation model using the following assumptions for 2005, 2004 and 2003:

	2005	2004	2003
	Risk-free Interest Rates	4.20%	2.56%
Expected Life	0.5 year	0.5 year	0.5 year
Volatility	0.46	0.84	0.86
Dividend Yield	—	—	—

The weighted average grant-date fair value per share of those purchase rights granted in 2005, 2004 and 2003 was \$2.19, \$1.37 and \$1.01, respectively.

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

The Company's cash and cash equivalents are deposited in demand and money market accounts of three financial institutions. 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.

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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 letter 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 group of customers in any particular geographic area. For the years ended December 31, 2005, January 1, 2005 and January 3, 2004 no customer accounted for greater than 10% of revenue. As of December 31, 2005, January 1, 2005 and January 3, 2004 no customers accounted for more than 10% of accounts receivable.

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 to incorporate the products or services into the Company's products.

### *Use of Estimates*

In accordance with accounting principles generally accepted in the United States of America, management utilizes certain estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expense during the reporting period. The primary estimates underlying the Company's financial statements include allowance for doubtful accounts receivable, reserves for obsolete and slow moving inventory, product warranty, income taxes and accrual for other liabilities. Actual results could differ from those estimates.

### *Fiscal Year*

The Company's fiscal year covers a 52 or 53 week period and ends on the Saturday nearest December 31. Fiscal year 2004 and 2005 included 52 weeks. Fiscal year 2003 included 53 weeks.

### *Net Income (loss) per Share*

Basic and diluted net income (loss) per share are computed by dividing net income (loss) for the year by the weighted average number of shares of common stock outstanding during the period. The calculation of diluted net income (loss) per share excludes potential common stock if their effect is anti-dilutive. Potential common stock consists of incremental common shares issuable upon the exercise of stock options. See Note 10.

### *Recent Accounting Pronouncements*

In December 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 123R, "Share-Based Payment — An Amendment of FASB Statements No. 123 and 95" ("SFAS 123R"). The new pronouncement replaces the existing requirements under SFAS 123 and APB 25. According to SFAS 123R, all forms of share-based payments to employees, including employee stock options and employee stock purchase plans, would be treated the same as any other form of compensation by recognizing the related cost

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in the statement of operations. This pronouncement eliminates the ability to account for stock-based compensation transactions using APB 25 and generally requires that such transactions be accounted for using a fair-value based method. The statement requires companies to assess the most appropriate model to calculate the value of the options. We currently use the Black-Scholes option pricing model to value options; however, we are currently assessing which model we may use in the future under the new statement and may deem an alternative model to be the most appropriate. The use of a different model to value options may result in a different fair value than would result from the use of the Black-Scholes option pricing model. In addition, there are a number of other requirements under the new standard that would result in different accounting treatment than is currently required. These differences include, but are not limited to, the accounting for the tax benefit on employee stock options and for stock issued under our employee stock purchase plan, and the presentation of these tax benefits within the statement of cash flows. We will adopt SFAS 123R using the prospective method of adoption.

In March 2005, the SEC issued Staff Accounting Bulletin No. 107, "*Share-Based Payment*" ("SAB 107"). SAB 107 provides guidance on the initial implementation of SFAS 123R. In particular, the statement includes guidance related to share-based payment awards for non-employees, valuation methods and selecting underlying assumptions such as expected volatility and expected term. SAB 107 also gives guidance on the classification of compensation expense associated with such awards and accounting for the income tax effects of those awards upon the adoption of SFAS 123R.

In April 2005, the SEC announced the adoption of a new rule that amends the effective date of SFAS 123R. The effective date of the new standard under these new rules for our financial statements is January 1, 2006. Adoption of this statement is expected to have a significant impact on our financial statements as we will be required to expense the fair value of our stock option grants and stock purchases under our employee stock purchase plan ("ESPP") rather than disclose the impact on our net loss within our footnotes, as is our current practice. The full impact of SFAS 123R on our financial statements and related disclosures is still being evaluated by management but is expected to be material to our results of operations. Our actual share-based compensation expense in 2006 will be dependent on a number of factors, including the amount of awards granted and the fair value of those awards at the time of grant.

In May 2005, the FASB issued SFAS No. 154, "*Accounting Changes and Error Corrections - replacement of APB Opinion No. 20 and FASB Statement No. 3*" ("SFAS 154"). SFAS 154 changes the accounting for and reporting of a change in accounting principle by requiring retrospective application to prior periods' financial statements of changes in accounting principle unless impracticable. SFAS 154 is effective for accounting changes made in fiscal years beginning after December 15, 2005. We do not expect the adoption of SFAS 154 to have a material impact on our results of operations, financial position or cash flows.

[Table of Contents](#)**3. Balance Sheet Detail**

Available-for-sale securities (in thousands):

	<u>Cost</u>	<u>Unrealized Gain (Loss)</u>	<u>Estimated Fair Value</u>	<u>Maturity Dates</u>
As of December 31, 2005, available-for-sale securities consisted of the following:				
Corporate notes	\$ 5,442	\$ (19)	\$ 5,423	2/06–6/06
Government agencies	3,364	(8)	3,356	1/06–3/06
Total	<u>\$ 8,806</u>	<u>\$ (27)</u>	<u>\$ 8,779</u>	

As of January 1, 2005, short term available-for-sale securities consisted of the following :

Corporate notes	<u>\$ 3,345</u>	<u>\$ (22)</u>	<u>\$ 3,323</u>	5/05 – 8/05
Total	<u>\$ 3,345</u>	<u>\$ (22)</u>	<u>\$ 3,323</u>	

As of January 1, 2005, long term available-for-sale securities consisted of the following :

Corporate notes	<u>\$ 4,312</u>	<u>\$ (12)</u>	<u>\$ 4,324</u>	2/06 – 5/06
Total	<u>\$ 4,312</u>	<u>\$ (12)</u>	<u>\$ 4,324</u>	

There were no realized capital gains or losses recognized in 2005, 2004 and 2003.

	<u>December 31, 2005</u>	<u>January 1, 2005</u>
Inventories:		
Raw materials and work in process	\$ 5,191	\$ 5,460
Finished goods	3,403	3,462
Total inventories	<u>\$ 8,594</u>	<u>\$ 8,922</u>
Property and Equipment:		
Equipment	\$ 4,937	\$ 4,264
Leasehold improvements	1,921	1,903
Less: accumulated depreciation and amortization	(5,744)	(5,315)
Property and equipment, net	<u>\$ 1,114</u>	<u>\$ 852</u>

Depreciation expense related to property and equipment was \$435,000, \$384,000 and \$703,000 for the years ended December 31, 2005, January 1, 2005 and January 3, 2004.

Accrued Expenses:

Accrued payroll, vacation and related expenses	\$ 1,671	\$ 1,100
Accrued warranty	1,129	933
Income taxes payable	552	783
Sales and use tax payable	220	1,277
Other accrued expenses	849	1,074
Total accrued expenses	<u>\$ 4,421</u>	<u>\$ 5,167</u>

**4. Bank Borrowings**

The Company has a revolving line of credit agreement with a bank expiring on October 5, 2006, which provides for borrowings of up to \$4.0 million at the bank's prime rate (7.25% at December 31, 2005).

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The agreement contains restrictive covenants including prohibiting payment of dividends without the bank's prior consent. There were no borrowings against the credit line at December 31, 2005.

### 5. Commitments and Contingencies

#### *Lease Agreements*

The Company leases its operating facilities under a noncancelable operating lease. In September 2003, the Company entered into a lease amendment for our facility in Mountain View. The original lease term of this facility, which ended in February 2004, was amended and extended until February 2009. The lease was also amended to grant the Company an option to renew this lease for an additional five year period beginning 2009 until 2014 at a base monthly rental amount to be negotiated at the time of the renewal. Rent expense totaled \$403,000, \$403,000 and \$606,000 for the years ended December 31, 2005, January 1, 2005 and January 3, 2004 respectively.

Future minimum lease payments under current operating leases at December 31, 2005 are summarized as follows (*in thousands*):

Fiscal Year	Operating Lease Payments
2006	\$ 402
2007	416
2008	429
2009	72
	\$ 1,319

#### *License Agreements*

The Company is obligated to pay royalties equivalent to 5% and 7.5% of sales on certain products under certain license agreements. Royalty expense was \$71,000, \$80,000 and \$93,000 for the years ended December 31, 2005, January 1, 2005 and January 3, 2004, respectively.

#### *Contingencies*

In October 2005, the Company filed suit against Synergetics, USA, Inc. for infringement of a patent. The Company seeks injunctive relief, monetary damages, treble damages, cost and attorneys' fees. Synergetics answered the Company's complaint in November 2005 and denied liability for patent infringement, filing counterclaims seeking a declaratory judgment that it did not infringe the Company's patent. Synergetics also brought three additional counterclaims for false advertising, commercial disparagement, trade libel, injurious falsehood, unfair competition, disparagement of property, slander of goods and defamation, under state and federal law, based upon allegations that the Company had raised safety issues involving Synergetics' product with the Food and Drug Administration and the public. Synergetics seeks monetary damages, costs and attorneys' fees. The Company's response to those counterclaims was a denial of wrongdoing and a reference to the expiration of the statute of limitations on those claims. Management believes that liabilities resulting from such proceedings, or 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 operation. While we believe it's not material to the company's operations, the company may incur significant dedication of management resources and legal costs in connection with this lawsuit.

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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 insurance.

### **6. Stockholders' Equity**

#### **Convertible Preferred Stock**

Our Articles of Incorporation authorize 2,000,000 shares of undesignated preferred stock. Preferred Stock may be issued from time to time in one or more series. As of December 31, 2005, we had no preferred stock issued and outstanding.

#### **Treasury Stock**

In December 1998, we instituted a stock repurchase program whereby up to 150,000 shares of our Common Stock may be repurchased in the open market. We plan to utilize all of the reacquired shares for reissuance in connection with our employee stock programs. In 2003, 2004 and 2005, no shares of Common Stock were repurchased. As of December 31, 2005 we have repurchased 103,000 shares of common stock. There are no plans to repurchase additional shares as the stock repurchase program has been discontinued in 2005.

#### **Stock Option Plans**

##### *Amended and Restated 1989 Incentive Stock Plan*

The Amended and Restated 1989 Plan (the "1989 Plan") provided for the grant of options and stock purchase rights to purchase shares of our Common Stock to employees and consultants. The terms of the 1989 Plan, which expired in August 1999, are substantially the same as the 1998 Plan described below.

##### *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

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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 our outstanding capital stock must not exceed five years. In the case of SPRs, unless the Administrator determines otherwise, we have a repurchase option exercisable upon the voluntary or involuntary termination of the purchaser's employment with us 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 us is the original price paid by the purchaser. As of December 31, 2005 and January 1, 2005, 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 expires in June 2008.

### *1995 Director Option Plan*

In October 1995, we adopted the 1995 Director Option Plan (the "Director Plan"), under which members of the Board of Directors are granted options to purchase 11,250 shares upon the first to occur of their appointment or the adoption of the Director Plan ("First Option") and an option to purchase 3,750 shares ("Subsequent Option") on July 1 of each year thereafter provided that he or she has served on the Board for at least the preceding six months. The options granted are at fair market value on the date of grant. The First Option becomes exercisable as to one-twelfth (1/12) of the shares subject to the First Option for each quarter over a three-year period. Each Subsequent Option becomes exercisable as to one-fourth (1/4) of the shares subject to the Subsequent Option for each quarter, commencing one quarter after the First Option and any previously granted Subsequent Options have become fully exercisable. Options granted under the Director Plan have a term of 10 years.

In the event of our merger with or into another corporation, resulting in a change of control, or the sale of substantially all of our assets, each Director Plan option becomes exercisable in full and shall be exercisable for 30 days after written notice to the holder of the event causing the change in control.

The Director Plan terminated in 2005.

### *Stand-Alone Option*

In July 2005, in connection with the employment of the Company's Chief Executive Officer, the Company's Board of Directors granted a stand alone option, outside of the Company's existing stock plans, to the Chief Executive Officer. The option entitles Mr. Caldwell to purchase up to 234,104 shares of the Company's common stock at an exercise price of \$6.07 per share. In conjunction with the employment of the Company's Chief Executive Officer, in consideration of services performed under a recruiting contract, the Company issued a warrant to purchase 25,000 shares of the Company's common stock at an exercise price of \$6.07 per share. The warrant is exercisable at any time and expires on July 5, 2008. The fair value of the warrants of \$87,000 was recorded as an expense for the twelve month period ended December 31, 2005. The fair value of the warrant was calculated using the Black-Scholes pricing model with the following assumptions: dividend yield 0 percent, contractual life of 3 years, risk free rates of 4.04 percent and volatility of 83 percent. At December 31, 2005, the warrant remains outstanding.

[Table of Contents](#)*2005 Employee Stock Purchase Plan*

Our 2005 Employee Stock Purchase Plan (the "Purchase Plan") was adopted by the Board of Directors in June 2005. The total number of shares of common stock reserved for issuance under the Purchase Plan at December 31, 2005 was 57,822. The Purchase Plan permits eligible employees (including officers) to purchase Common Stock through payroll deductions, which may not exceed 10% of an employee's compensation. No employee may purchase more than \$25,000 worth of stock in any calendar year or more than 2,000 shares of Common Stock in any twelve-month period. The price of shares purchased under the Purchase Plan is 85% of the lower of the fair market value of the Common Stock at the beginning of the offering period or the end of the offering period.

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

	Shares Available for Grant	Outstanding Options		
		Number of Shares	Aggregate Price	Weighted Average Exercise Price
Balances, December 28, 2002	399,747	1,700,863	8,687	5.11
Additional shares reserved	270,000	—	—	—
Options granted	(395,000)	395,000	1,516	3.84
Options exercised		(52,466)	(179)	3.40
Options cancelled	(649)			
Options terminated	39,114	(39,114)	(189)	4.83
Balances, January 3, 2004	313,212	2,004,283	9,835	4.91
Additional shares reserved	270,000	—	—	—
Options granted	(214,750)	214,750	1,379	6.42
Options exercised		(294,852)	(1,085)	3.68
Options cancelled	(15,000)			
Options terminated	100,789	(100,789)	(701)	6.95
Balances, January 1, 2005	454,251	1,823,392	9,428	5.18
Additional shares reserved	434,104	—	—	—
Options granted	(622,050)	622,050	3,791	6.09
Warrants issued	(25,000)	25,000		
Options exercised		(183,873)	(663)	3.60
Options cancelled	(78,355)			
Options terminated	132,566	(132,566)	(866)	6.53
Balances, December 31, 2005	295,516	2,154,003	\$ 11,845	\$5.50



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The following table summarizes information with respect to stock options outstanding at December 31, 2005:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding at 12/31/05	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable at 12/31/05	Weighted Average Exercise Price
\$2.94- \$3.50	271,482	7.17	\$ 3.36	176,327	\$ 3.38
\$3.52 - \$3.98	162,558	6.13	3.67	138,433	3.68
\$4.00 - \$4.00	284,289	1.80	4.00	284,289	4.00
\$4.01 - \$5.00	222,710	5.50	4.42	177,420	4.41
\$5.08 - \$5.50	228,334	7.01	5.24	84,272	5.29
\$5.56 - \$6.00	119,838	8.62	5.64	38,828	5.62
\$6.07 - \$6.07	300,000	9.51	6.07	0	0.00
\$6.19 - \$7.25	228,154	7.85	6.66	102,821	6.72
\$7.38 - \$9.00	247,950	5.03	8.49	175,431	8.62
\$9.06 - \$14.88	88,688	4.47	10.22	83,063	10.30
<b>\$2.94 - \$14.88</b>	<b>2,154,003</b>	<b>6.31</b>	<b>\$ 5.50</b>	<b>1,260,884</b>	<b>5.35</b>

At January 1, 2005 and January 3, 2004 options to purchase 1,823,392 and 1,354,937 shares of common stock were exercisable at a weighted average exercise price of \$ 5.36 and \$5.29, respectively.

### 7. 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 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. On April 1, 2000 the Company commenced a Company match for the 401(k) in the amount of 50% of employee contributions up to an annual maximum of \$1,000 per year. The Company contributions totaled \$94,000 in 2005, \$88,000 in 2004 and \$89,000 in 2003.

### 8. Income Taxes

The provision for income taxes includes:

	Year Ended December 31, 2005	Year Ended January 1, 2005	Year Ended January 3, 2004
Current:			
Federal	\$ 59	\$ 212	\$ 19
State	31	14	9
	90	226	28
Deferred:			
Federal	451	(519)	(148)
State	125	(62)	(87)
	576	(581)	(235)
<b>Income tax provision (benefit)</b>	<b>\$ 666</b>	<b>\$ (355)</b>	<b>\$ (207)</b>

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

	Year Ended December 31, 2005	Year Ended January 1, 2005	Year Ended January 3, 2004
Income tax provision at statutory rate	34%	34%	34%
State income taxes, net of federal benefit	6%	8%	6%
Tax exempt interest	0%	0%	0%
Nondeductible permanent differences	1%	(5%)	19%
Research and development credits	(13%)	12%	(164%)
Other	0%	(2%)	(22%)
Effective tax rate	<u>28%</u>	<u>47%</u>	<u>(127%)</u>

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):

	December 31, 2005	January 1, 2005
Fixed assets	\$ 558	\$ 640
Accrued liabilities	595	1,039
Allowance for excess and obsolete inventories	599	514
Research credit	514	626
State tax	1	1
Allowance for doubtful accounts	215	184
Other	6	69
Net deferred tax asset	<u>\$ 2,488</u>	<u>\$ 3,073</u>

As of December 31, 2005, the Company had Federal and State research credit carryforwards of approximately \$192,000 and \$451,000 available to offset future liabilities. The Federal credits will begin expiring in 2022 if not used. The state research credits do not expire.

## 9. Major Customers and Business Segments

The Company operates in two reportable segments: the ophthalmology medical device segment and the dermatology medical device segment. In both segments, the Company develops, manufactures and markets medical devices. Our revenues arise from the sale of consoles, delivery devices, disposables and service and support activities.

In the years ended December 31, 2005, January 1, 2005 and January 3, 2004, no customer individually accounted for more than 10% of our revenue.

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

	Year Ended December 31, 2005	Year Ended January 1, 2005	Year Ended January 3, 2004
United States	\$ 22,713	\$ 19,894	\$ 20,072
Europe	\$ 7,138	6,498	5,297
Rest of Americas	\$ 1,703	631	1,000
Asia/Pacific Rim	\$ 5,475	5,787	5,330
	<u>\$ 37,029</u>	<u>\$ 32,810</u>	<u>\$ 31,699</u>

Revenues are attributed to countries based on location of customers.

In the years ended December 31, 2005, January 1, 2005 and January 3, 2004, no country individually accounted for more than 10% of the Company's sales, except for the United States, which accounted for 61.4% of sales in 2005, 60.6% in 2004 and 63.3% in 2003.

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Information on reportable segments for the three years ended December 31, 2005, January 1, 2005, and January 3, 2004 is as follows:

	<b>Year Ended December 31, 2005</b>		
	<b>Ophthalmology Medical Devices</b>	<b>Dermatology Medical Devices</b>	<b>Total</b>
Sales	\$ 30,663	\$ 6,366	\$ 37,029
Direct cost of goods sold	\$ 10,374	\$ 3,138	\$ 13,512
Direct gross margin	\$ 20,289	\$ 3,228	\$ 23,517
Total unallocated indirect costs			\$ 21,708
Income from operations			\$ 1,809

  

	<b>Year Ended January 1, 2005</b>		
	<b>Ophthalmology Medical Devices</b>	<b>Dermatology Medical Devices</b>	<b>Total</b>
Sales	\$ 27,753	\$ 5,057	\$ 32,810
Direct cost of goods sold	\$ 9,876	\$ 2,898	\$ 12,774
Direct gross margin	\$ 17,877	\$ 2,159	\$ 20,036
Total unallocated indirect costs			\$ 21,112
Loss from operations			\$ (1,076)

  

	<b>Year Ended January 3, 2004</b>		
	<b>Ophthalmology Medical Devices</b>	<b>Dermatology Medical Devices</b>	<b>Total</b>
Sales	\$ 26,160	\$ 5,539	\$ 31,699
Direct cost of goods sold	\$ 9,217	\$ 2,782	\$ 11,999
Direct gross margin	\$ 16,943	\$ 2,757	\$ 19,700
Total unallocated indirect costs			\$ 19,748
Loss from operations			\$ (48)

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Indirect costs of manufacturing, research and development and selling, general and administrative costs are not allocated to the segments.

The Company's assets and liabilities are not evaluated on a segment basis. Accordingly, no disclosure on segment assets and liabilities is provided.

#### 10. Computation of Net Income Per Common Share and Per Diluted Common Share

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

	Year Ended December 31, 2005	Year Ended January 1, 2005	Year Ended January 3, 2004
Net income (loss)	\$ 1,671	\$ (402)	\$ 371
Denominator — Net income (loss) per common share			
Weighted average common stock outstanding	7,405	7,200	6,933
Effect of dilutive securities			
Weighted average common stock options	475	—	139
Total weighted average stock and options outstanding	<u>7,880</u>	<u>7,200</u>	<u>7,072</u>
Net income (loss) per common share	<u>\$ 0.23</u>	<u>\$ (0.06)</u>	<u>\$ 0.05</u>
Diluted net income (loss) per common share	<u>\$ 0.21</u>	<u>\$ (0.06)</u>	<u>\$ 0.05</u>

In 2005 and 2003, there were 454,918 and 791,406 outstanding options to purchase shares, respectively, at weighted average exercise prices of \$8.48 and \$6.99 per share, respectively, that were not included in the computation of diluted net income (loss) per common share since, in each case, the exercise price of the options exceeded the market price of the common stock. In 2004, there were 463,588 options outstanding at a weighted average exercise price of \$8.65 that were not included in the computation of diluted net loss per common share because their effect was antidilutive. These options could dilute earnings per share in future periods.

#### 11. Selected Quarterly Financial Data, (Unaudited)

	Quarter			
	First	Second	Third	Fourth
	(In thousands, except per share amounts)			
Year Ended December 31, 2005				
Sales	\$ 8,145	\$ 9,387	\$ 9,081	\$ 10,416
Gross profit	\$ 3,678	\$ 4,545	\$ 4,879	\$ 5,073
Net income (loss)	\$ (20)	\$ 430	\$ 879	\$ 381
Net income (loss) per common share	\$ (0.00)	\$ 0.06	\$ 0.12	\$ 0.05
Diluted net income (loss) per common share	\$ (0.00)	\$ 0.05	\$ 0.11	\$ 0.05
Year Ended January 1, 2005				
Sales	\$ 7,392	\$ 8,109	\$ 8,178	\$ 9,131
Gross profit	\$ 3,215	\$ 3,807	\$ 3,470	\$ 4,396
Net income (loss)	\$ (17)	\$ 133	\$ (720)	\$ 202
Net income (loss) per common share	\$ (0.00)	\$ (0.02)	\$ (0.10)	\$ 0.03
Diluted net income (loss) per common share	\$ (0.00)	\$ (0.02)	\$ (0.10)	\$ 0.03

**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.**

*a) Evaluation of disclosure controls and procedures.*

The Company's management evaluated, with the participation of its Chief Executive Officer (CEO) and its Chief Financial Officer (CFO), the effectiveness of the design and operation of its disclosure controls and procedures (as defined in Rule 13A-15(e) and Rule 15d-15(e) of the Securities Exchange Act of 1934 (the "'34 Act") as of the end of the period covered by this report.

Disclosure controls and procedures are designed with the objective of ensuring that (i) information required to be disclosed in the Company's reports filed under the '34 Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) information is accumulated and communicated to management, including the CEO and CFO, is appropriate to allow timely decisions regarding required disclosure. Internal control procedures, which are designed with the objective of providing reasonable assurance that the Company's transactions are properly authorized, its assets are safeguarded against unauthorized or improper use and its transactions are properly recorded and reported, are intended to permit the preparation of the Company's financial statements in conformity with generally accepted accounting principles. To the extent that elements of our internal control over financial reporting are included within our disclosure controls and procedures, they are included in the scope of our quarterly controls evaluation.

Based on that evaluation, the CEO and CFO concluded, due to the material weakness described below, that as of the end of the period covered by this report, the disclosure controls and procedures were ineffective in ensuring that all material information required to be disclosed in the reports the Company files and submits under the '34 Act has been made known to them on a timely basis and that such information has been properly recorded, processed, summarized and reported, as required. As discussed in (b) below, the Company is taking steps to remediate the material weakness.

In connection with the annual audit of the Company's financial statements as of December 31, 2005, the Company's independent registered public accounting firm communicated to the Company's management and the Audit Committee of the Board of Directors that they had identified a control deficiency that existed in the design or operation of the Company's internal controls over financial reporting that they considered to be a material weakness, because the control deficiency resulted in more than a remote likelihood that a material misstatement could occur in the Company's annual financial statements and not be prevented or detected. The material weakness identified by the Company's independent accountants relates to a failure to maintain adequate period-end review procedures over general ledger accounts. As a result, an error in a system generated custom inventory report and errors in two key spreadsheets related to warranty and deferred revenue resulted in incorrect entries being recorded to the financial statements which were not identified and corrected by management in a timely manner.

*b) Changes in internal control over financial reporting.*

In response to the deficiencies noted above, the Company has identified the following corrective actions necessary to address the material weakness described above, as follows:

- Implement additional controls over the preparation and review of key spreadsheets
- Implement automated general ledger reports to replace existing key spreadsheets where possible,
- Correct a system generated custom report to include additional information necessary to prepare accurate financial information
- Implement additional review procedures
- Enhance the current capabilities of the finance function.

The Company has begun implementing these corrective actions and believes that these corrective actions, once implemented, will mitigate the material weakness that was identified.

In addition, we reviewed our internal controls during the quarter ended December 31, 2005, and there were no other changes in our internal controls or in other factors that could significantly affect those controls during the period covered by this report.

**Item 9B. Other Information**

Not applicable.

**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 2006 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 8, 2006.

**Item 10. Directors and Executive Officers of the Registrant**

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 "Proposal One – Election of Directors – 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**

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 Five – Ratification of Appointment of Independent Accountants" in our Proxy Statement.

**PART IV****Item 15. Exhibits, Financial Statement Schedules and Reports on Form 8-K****Page in  
Form 10-K  
Report**

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

**1. Financial Statements**

[Report of Independent Registered Public Accounting Firm](#)

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[Consolidated Balance Sheets as of December 31, 2005 and January 1, 2005](#)

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[Consolidated Statements of Operations for the years ended December 31, 2005, January 1, 2005 and January 3, 2004](#)

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[Consolidated Statements of Stockholders' Equity for the years ended December 31, 2005, January 1, 2005 and January 3, 2004](#)

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[Consolidated Statements of Cash Flows for the years ended December 31, 2005, January 1, 2005 and January 3, 2004](#)

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[Consolidated Statements of Comprehensive Income \(Loss\) for the years ended December 31, 2005, January 1, 2005 and January 3, 2004](#)

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[Notes to Consolidated Financial Statements](#)

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**2. Financial Statement Schedule**

The following financial statement schedule of IRIDEX Corporation for the years ended December 31, 2005, January 1, 2005 and January 3, 2004 is filed as part of this Annual Report and should be read in conjunction with the Consolidated Financial Statements of IRIDEX Corporation.

[Schedule II – Valuation and Qualifying Accounts](#)

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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**

<u>Exhibits</u>	<u>Exhibit Title</u>	
3.1(1)	Amended and Restated Certificate of Incorporation of Registrant.	
3.2(2)	Amended and Restated Bylaws of Registrant.	
10.1(1)	Form of Indemnification Agreement with directors and officers.	
10.2(1)	2005 Employee Stock Purchase Plan.	
10.3(5)	Employment Agreement with Barry G. Caldwell dated July 5, 2005.	
10.4(6)	Executive Transition Agreement entered into by and between the Company and Theodore A. Boutacoff dated April 28, 2005.	
10.5(6)	Amended and Restated Severance and Change of Control Agreement entered into by and between the Company and Larry Tannenbaum on April 29, 2005.	
10.6(4)	Lease Agreement dated December 6, 1996 by and between Zappettini Investment Co. and the Registrant, as amended.	
10.7(3)	1998 Stock Option Plan, as amended.	
21.1(1)	Subsidiaries of Registrant.	
23.1	Consent of Independent Registered Public Accounting Firm.	
24.1	Power of Attorney (See page 69).	
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	

## Table of Contents

<u>Exhibits</u>	<u>Exhibit Title</u>
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.

- 
- (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 in Registrant's Report on Form 10-Q for the quarter ended October 3, 1998.
  - (3) Incorporated by reference to the Exhibits in Registrant's Proxy Statement for the Company's 1998 Annual Meeting of Stockholders which was filed April 30, 1998.
  - (4) Incorporated by reference to the Exhibits in Registrant's Report on Form 10-Q for the quarter ended September 27, 2003.

### **Trademark Acknowledgments**

IRIDEX, the IRIDEX logo, IRIS Medical, OcuLight, IQ810, VariLite, DioLite XP, SmartKey, EndoProbe and Apex are our registered trademarks. IRIDERM, G-Probe, DioPexy, DioVet, TruFocus, TrueCW, UltraView, DioLite 532, Long Pulse, MicroPulse Scanlite Scanner, ColdTip Handpiece, Varisport Handpiece and EasyFit 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.



**IRIDEX CORPORATION AND SUBSIDIARIES**  
**VALUATION AND QUALIFYING ACCOUNTS**  
*(in thousands)*

Description	Balance at Beginning of The Period	Charged to Costs and Expenses	Deductions	Balance at End of The Period
Balance for the year ended January 3, 2004:				
Allowance for doubtful accounts receivable	\$ 262	\$ —	\$ (142)	\$ 120
Provision for inventory	\$ 1,106	\$ —	\$ (63)	\$ 1,043
Balance for the year ended January 1, 2005:				
Allowance for doubtful accounts receivable	\$ 120	\$ 376	\$ (30)	\$ 466
Provision for inventory	\$ 1,043	\$ 694	\$ —	\$ 1,737
Balance for the year ended December 31, 2005:				
Allowance for doubtful accounts receivable	\$ 466	\$ 132	\$ (39)	\$ 559
Provision for inventory	\$ 1,737	\$ 407	\$ (89)	\$ 2,055



**Exhibit Index**

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3.2(2)	Amended and Restated Bylaws of Registrant.
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10.7(3)	1998 Stock Option Plan, as amended.
21.1(1)	Subsidiaries of Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (See page 69).
31.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 906 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.

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  - (3) Incorporated by reference to the Exhibits in Registrant's Proxy Statement for the Company's 2005 Annual Meeting of Stockholders which was filed April 29, 2005.
  - (4) Incorporated by reference to the Exhibits in Registrant's Report on Form 10-Q for the quarter ended September 27, 2003.
  - (5) Incorporated by reference to the Exhibits filed with the Registrant's Report on Form 8-K dated July 5, 2005.
  - (6) Incorporated by reference to the Exhibits filed with the Registrant's Report on Form 8-K dated April 28, 2005.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Forms S-8 (No. 333-117885, 333-127716, 333-32161, 333-57573, 333-86091, 333-45736, 333-67480, 333-97541 and 333-107700) of Iridex Corporation of our report dated March 31, 2006 relating to the financial statements and financial statement schedules which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

San Jose, California  
March 31, 2006

**EXHIBIT 31.1**

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER  
PURSUANT TO SECTION 13(a) or 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934  
AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Barry G. Caldwell, certify that:

1. I have reviewed this report on Form 10-K of IRIDEX Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statement were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b) Evaluated the effectiveness of the registrant's disclosure control and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c) Disclosed in this report any changes in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of the annual report) that has materially affected, or is reasonably likely to materially affect the registrant's internal control over financial reporting;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2006

By: /s/ BARRY G. CALDWELL

Name: Barry G. Caldwell

Title: President and Chief Executive Officer

(Principal Executive Officer)

**EXHIBIT 31.2**

**CERTIFICATION OF CHIEF FINANCIAL OFFICER**  
**PURSUANT TO SECTION 13(a) or 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
**AS ADOPTED PURSUANT TO**  
**SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Larry Tannenbaum certify that:

1. I have reviewed this report on Form 10-K of IRIDEX Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statement made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - (b) Evaluated the effectiveness of the registrant's disclosure control and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures , as of the end of the period covered by this report based on such evaluation; and
  - (c) Disclosed in this report any changes in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of the annual report) that has materially affected, or is reasonably likely to materially affect the registrant's internal control over financial reporting;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2006

By: /s/ LARRY TANNENBAUM

Name: Larry Tannenbaum

Title: Chief Financial Officer and Vice President, Administration  
(Principal Financial and Accounting Officer)

**EXHIBIT 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**

I, Barry G. Caldwell, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of IRIDEX Corporation on Form 10-K for the fiscal year ended December 31, 2005 (i) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and (ii) that information contained in such Annual Report on Form 10-K fairly presents, in all material respects, the financial condition and results of operations of IRIDEX Corporation.

Date: March 31, 2006

By: /s/ BARRY G. CALDWELL

Name: Barry G. Caldwell

Title: President and Chief Executive Officer  
(Principal Executive Officer)

**EXHIBIT 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**

I, Larry Tannenbaum, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of IRIDEX Corporation on Form 10-K for the fiscal year ended December 31, 2005 (i) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and (ii) that information contained in such Annual Report on Form 10-K fairly presents, in all material respects, the financial condition and results of operations of IRIDEX Corporation.

Date: March 31, 2006

By: /s/ LARRY TANNENBAUM

Name: Larry Tannenbaum

Title: Chief Financial Officer and Vice President, Administration  
(Principal Financial and Accounting Officer)