

**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 January 1, 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 whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 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 an accelerated filer (as defined in Rule 12b-2 of the Act.) Yes No

The aggregate market value of the voting common equity held by non-affiliates of the Registrant was approximately \$ 32,821,341, as of July 3, 2004, 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 16, 2005, Registrant had 7,427,148 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain parts of the Proxy Statement for the Registrant's 2005 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; the 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; favorable Center for Medicare and Medicaid coverage decisions regarding AMD procedures that use our products; 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 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 semiconductor-based laser systems 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 68 independent distributors into 107 countries. Total product sales in 2004, 2003 and 2002 were \$32.8 million, \$31.7 million and \$30.6 million respectively, which generated a net income (loss) for those corresponding years of (\$402,000), \$371,000 and \$150,000. The net loss for 2004 of (\$402,000) included a one-time \$1.0 million charge to establish a reserve for sales taxes and interest, which the Company chose not to retroactively collect from our customers.

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. The current family of ophthalmology laser systems, which accounts for the majority of our revenues, is used for ophthalmic applications primarily in hospitals, 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 \$27.8 million, \$26.2 million and \$24.1 million to our total revenues in 2004, 2003 and 2002, respectively. Our dermatology products treat skin conditions, primarily vascular and pigmented lesions and remove unwanted hair. Our dermatology laser systems are the DioLite 532, the Apex 800 and the VariLite Dual Wavelength Laser systems. Our dermatology products are primarily used in the practitioner’s office and contributed \$5.0 million, \$5.5 million and \$6.5 million to our total revenues in 2004, 2003 and 2002, respectively. Each ophthalmic and dermatology laser system consists of a small, portable laser console and delivery devices, primarily for hospital and office-based use by ophthalmologists and dermatologists.

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We believe that our semiconductor-based systems were among the first to be developed and since our first shipment in 1990, more than 7,100 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 Web site at www.irdex.com, however, the information on, or that can be accessed through, our Web site is not part of this report. As used in this 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 and cost-effective medical laser systems. The key elements of our strategy are:

Broaden Product Lines. 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 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 Easy View 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 the 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 532 nm and 940 nm wavelengths for added clinical versatility and convenience for the physician. 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 development to improve the performance of our systems and broaden our product offerings. We also intend to develop additional technologies which can more cost effectively address the needs of the ophthalmic and dermatology markets.

Develop and Validate New Applications. We seek to develop and validate applications that are less costly, reduce side effects and achieve better clinical results than existing treatments. The objectives of developing new 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. An

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example of this is continued development of Minimum Intensity Photocoagulation (MIP) protocols. MIP is a laser treatment approach pioneered by IRIDEX, which uses our OcuLight infrared lasers to maximize preservation of sensitive retinal tissues while stimulating a therapeutic effect. We believe that maintaining leadership 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. Our products are currently being used in multiple studies in the United States and internationally to demonstrate the clinical benefits of MIP protocols. For example, our OcuLight SLx laser has been used in several studies to treat the various stages of both dry and wet forms of age-related macular degeneration (or AMD). We announced in October 1999 that a clinical pilot study on occult wet AMD produced results supporting that Transpupillary Thermotherapy (or TTT) was effective in improving or stabilizing vision in 75% of patients with a procedure using our OcuLight infrared laser photocoagulator. In November 2001, we announced that enrollment for the PTAMD study on dry AMD was completed as sufficient enrollment had been achieved to detect a clinically relevant difference in the clinical outcomes of the study. 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 sham and that further subgroup analysis would be conducted. Since that time, interim results of subgroup analysis has 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. In addition, two papers were recently published in the British Journal of Ophthalmology showing the effectiveness of MIP for treating diabetic retinopathy. Likewise, the IRIDEX family of dermatology lasers uses MIP to provide effective and gentle laser procedures. MIP technology is also important for dermatology applications where skin protection and patient comfort combined with effective outcome are essential. The DioLite 532 and VariLite treatment parameters are optimized to close damaged blood vessels and remove pigmented spots quickly and effectively while minimizing injury to the non-target tissue for a “bruise-free” result. 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.”

Provide Total Disease Management. We intend to expand our product offering by utilizing a total disease management approach. We pursue this on the therapeutic side by increasing the number of delivery devices and disposable EndoProbes tailored for use in procedures that treat specific diseases. We are also pursuing this on the diagnostic side by developing adjunctive visualization systems which could be used to either identify patients who require therapy, target laser therapy more accurately, or assess the adequacy of therapy. Examples of products we have already introduced which may be utilized for both visualization and treatment include our TruFocus Laser Indirect Ophthalmoscope and our line of clear view Slit Lamp Adapters, such as the Easy View. We believe that a significant opportunity exists to provide additional delivery devices used in treatment procedures and adjunctive visualization systems. By pursuing both delivery and diagnosis systems we intend to provide total disease management solutions for our customers.

Develop New Markets Through Strategic Alliances. We intend to establish strategic alliances in order to expedite and lower the cost of developing and bringing to market new products, both to the ophthalmology and dermatology markets and to markets not currently addressed by our products. Through these alliances, we will seek access to technologies that we do not currently possess. 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 in the future,

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in order to gain access to new markets for our products. 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, sometimes referred to as EndoProbes, 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 we develop new applications. 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 has an average sales price of approximately \$140.

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

Ophthalmology Photocoagulator Consoles.

The OcuLight family makes up the world’s largest installed base of solid-state ophthalmic lasers. Widely accepted for their reliability, performance, ease of use, and portability, OcuLight lasers are used for the office or operating room environments. There are no special electrical or plumbing requirements needed for the lasers contributing to their low cost of ownership.

Infrared (810 nm) Product Family: The IQ 810 is our top-of-the-line solid-state infrared console for ophthalmologists. The IQ 810 features interactive software for ease of use and clinical versatility, advanced waveform capability for performing conventional or MIP treatments, and the widest range of delivery devices for maximum clinical versatility. The OcuLight SLx is the industry standard in infrared systems and is designed to bridge conventional and emerging laser photocoagulation procedures with its unique Tri-Mode capability. The OcuLight SL laser is the specialty laser for ophthalmologists treating retinopathy of prematurity, glaucoma, or intraocular tumors.

Visible (or Green) Photocoagulator Family. The OcuLight GLx is the top-of-the line green Photocoagulator representing the latest in technological innovation. It offers 1.5 Watts of power to the cornea and is compatible to the widest array of delivery devices. The OcuLight GL was the first portable green laser photocoagulator and has become the industry standard in solid-state systems. This laser offers the greatest value to a practice. The green lasers perform the same clinical applications as traditional argon gas-tube lasers but eliminate the installation and maintenance costs associated with that technology.

In December 2002, we commenced shipment of the Millennium Endolase module, which is sold exclusively to Bausch & Lomb for use in their Millennium Microsurgical System. It integrates 532nm photocoagulator capability into Bausch & Lomb’s array of microsurgical capabilities. The Millennium Endolase module is compatible with the IRIDEX EndoProbe handpieces and Laser Indirect Ophthalmoscope.

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Combination Infrared/Visible Photocoagulator Consoles. The OcuLight Symphony Laser Delivery System, which we introduced in October 2002, is used by the ophthalmologist 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. We believe that this product offers a unique value-added proposition and the efficiency of dual laser wavelength delivery in a single product.

Dermatology Laser Consoles. Dermatology lasers offer advanced, solid-state semiconductor-based technology. Lasers are reliable, portable, efficient and clinically versatile. The systems are easy to set up and operate and do not require special cooling or electrical requirements. The DioLite 532 is an advanced, compact laser system available for the treatment of vascular and pigmented skin lesions. The 532 nm is used to treat superficial vascular lesions and pigmented lesions and can also be used for laser facial treatment when combined with the ScanLite product. The system offers treatment parameters for safe, predictable, and clinically effective results. The more recently introduced VariLite is a dual wavelength system offering 532 nm and 940 nm wavelengths in a clinically versatile and convenient package. This laser can perform all the applications of the DioLite 532 as well as treat acne, melasma, and cutaneous lesions. We believe that the smaller overall sizes, lower weights and low power requirements to operate represent distinct advantages of our dermatology laser consoles over competing products.

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. The indirect ophthalmoscope is designed to be worn on the physician's head during 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. 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 over 50 variations of 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 2004, we introduced the EasyView slit lamp adapter and IQ Slit Lamp Adapter with Fibercheck.

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 single use EndoProbe is used for endophotocoagulation, a retinal treatment procedure performed in the hospital operating room or surgery center. These sterile disposable probes are available in tapered, angled, fluted and illuminating styles. In 2003 and the first quarter of

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2004, we introduced four additions to our EndoProbe product line, including straight and angled illuminating laser probes, a 25 gauge probe and an aspirating probe.

G-Probe. The G-Probe is used in procedures to treat medically and surgically uncontrolled glaucoma, in many instances replacing cyclocryotherapy, or local freezing of eye tissue. 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.

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 is a computer pattern generator with integrated controls designed to enhance the capabilities of the DioLite 532 and VariLite laser systems. It allows rapid and uniform treatment of large-area vascular and pigmented skin lesions including port wine stains, matted telangiectasia, and cafe au lait stains as well as laser facial treatments.

Apex 800 ColdTip Handpiece. The ColdTip Handpiece is a handheld instrument used with the Apex 800 for large hair removal. It offers subzero contact cooling of the epidermis to allow the use of higher treatment fluences for improved treatment effectiveness and patient comfort.

Apex 800 Varispot Handpiece. The VariSpot Handpiece is a hand held instrument used with the Apex 800 for area hair removal. It offers an aiming beam which aids visualization of the target area allowing precise treatment.

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. The chart also lists the procedures for treating skin diseases that can utilize our dermatology laser systems.

<u>Condition</u>	<u>Procedure</u>	<u>Console</u>	<u>Delivery Devices</u>
<i>Ophthalmology Treatments:</i>			
Age-related Macular Degeneration	Retinal Photocoagulation	Infrared & Visible	Slit Lamp Adapter
Diabetic Retinopathy			

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<u>Condition</u>	<u>Procedure</u>	<u>Console</u>	<u>Delivery Devices</u>
Macular Edema	Grid Retinal Photocoagulation	Infrared & Visible	Slit Lamp Adapter & Operating Microscope Adapter,
	Focal Retinal Photocoagulation	Visible	Slit Lamp Adapter
Proliferative	Pan-Retinal Photocoagulation	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 Detachment	Retinopexy Retinal Photocoagulation	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
Dermatology Treatments:			
Vascular Lesions	Selective Photothermolysis	Visible & Infrared	DioLite Handpiece, VariLite Handpiece
Pigmented Lesions	Selective Photothermolysis	Visible & Infrared	DioLite Handpiece, VariLite Handpiece
Cutaneous Lesions	Selective Photothermolysis	Visible	VariLite Handpiece
Laser Facial	Selective Photothermolysis	Visible	ScanLite Scanner
Hair Removal	Selective Photothermolysis	Infrared	Cold Tip Handpiece, Varispot Handpiece, VariLite

Research and Development

Our research and development activities are performed internally by our research and development staff which is comprised of 17 individuals. From time to time, we supplement our internal research and development staff by hiring consultants with specialized expertise. Research and development 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. Our expenditures for research and development totaled approximately \$4.5 million, \$4.0 million and \$4.3 million in 2004, 2003 and 2002, respectively. We expect to continue to devote a significant portion

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of our resources to our research and development efforts for new products and new applications for existing products. 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.

We are continuing to develop MIP protocols. MIP is a laser treatment approach pioneered by IRIDEX, which uses our OcuLight SLx infrared lasers to maximize preservation of sensitive retinal tissues while stimulating a therapeutic effect. We believe that maintaining leadership 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.

We are supporting pre-clinical and clinical studies to develop new photocoagulation treatments and applications using MIP protocols. The objectives of developing new 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 promising 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. Favorable results of a pilot TTT study were published in October 1999. We announced results from a multi-center randomized trial called the TTT4CNV Trial, which are discussed in the section titled "We are Dependent on the Successful Outcome of Clinical Trials of Our Products and New Applications Using Our Products."

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). In November 2001, we announced that enrollment for the PTAMD trial was completed as sufficient enrollment had been achieved to detect a clinically relevant difference in the clinical outcomes of the study. This trial treats patients with dry AMD using our OcuLight infrared laser systems with the objective of determining whether patient vision is better as a result of treatment compared to no treatment; and secondarily, to determine whether treatment reduces the rate of progression of the disease from the dry form of AMD to the wet form of AMD. We expect results of this trial to be released prior to 2006 year end.

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.

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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.

Customers and Customer Support

Our products are currently sold to general ophthalmologists, as well as 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 2004, 2003 or 2002. 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 20,000 ophthalmologists in the United States and 50,000 worldwide who are each potential customers for at least one laser system. 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, 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. We believe that our superior customer service and technical support distinguish our product offerings from those of our competitors. Our customer support representatives assist customers with orders, shipments, 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 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. As of January 1, 2005, our direct sales force consisted of 13 employees, with 3 open positions, 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 39.4%, 36.7% and 36.1% of our sales in 2004, 2003 and 2002, 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

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and the Asia/Pacific Rim region. Our products are sold internationally through our 66 independent distributors into 107 countries. International sales are administered through our corporate headquarters in Mountain View, California, along with four international area sales managers located overseas. 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, and advertising in trade and academic journals and newsletters. We annually participate in approximately 91 trade shows or meetings in the United States and approximately 60 trade shows or meetings internationally. These meetings allow us to present our products to existing and prospective buyers.

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. We believe that the trend toward management of health care costs in the United States will lead to increased awareness of and emphasis on disease prevention and cost-effective treatments and, as a result, will increase demand for our ophthalmic products.

We collaborate with our customers to enhance our ability to identify new applications for our products, validate new procedures using our products, and expedite regulatory clearances and approvals of new products and applications. Customers include key opinion leaders who are often the heads of the departments in which they work or professors at universities. We believe that these luminaries in the field of ophthalmology and dermatology are key to the successful introduction of new products and the subsequent acceptance of these new products by the general market. Acceptance of our products by these early adopters is key to our strategy in the validation of our new products.

Operations

The manufacture of our infrared and visible light photocoagulators and the related delivery devices is a highly complex and precise process. Completed systems must pass quality control and reliability tests before shipment. Our manufacturing activities consist of specifying, sourcing, assembling and testing of components and certain subassemblies for assembly into our final product. As of January 1, 2005, we had a total of 52 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 13485:1996 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.

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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 a 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 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 laser competitors in ophthalmology are Lumenis Ltd., Carl Zeiss Meditec AG, Alcon Inc., Quantel, Laserex and Nidek, Inc. 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) and Macugen (Eyeteck) compete rigorously with traditional laser procedures. Our principal competitors in dermatology are Palomar Technologies, Laserscope, Candela Corporation, Lumenis Ltd., and Cutera Inc. 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 four 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 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.

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. Proprietary information agreements with employees, consultants and others may be breached, and we may not have adequate remedies for any breach. Additionally, 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 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 regard 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.

Any claims that we may be infringing upon patents or other proprietary intellectual property owned by others, 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, require us to develop noninfringing technology or require us to enter into royalty or licensing agreements. An adverse determination in a judicial or administrative proceeding and the 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. Conversely, litigation may be necessary to enforce patents issued to us, to protect trade secrets or know-how owned by us or to determine the enforceability, scope and validity of the proprietary rights of others. Both the defense and prosecution of intellectual property suits or interference proceedings are costly and time consuming. 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 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 four to twelve months or longer 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, 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.

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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 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 premarket 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

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upon us with respect to design, development, manufacturing and quality assurance activities. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of the California Department of Health Services, or CDHS, to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our subcontractors.

Labeling and promotion activities are subject to scrutiny by the FDA and, in certain instances, by the Federal Trade Commission. The FDA actively enforces regulations prohibiting marketing of products for unapproved uses. We and our products are also subject to a variety of state laws and regulations in those states or localities where our products are or will be marketed. Any applicable state or local regulations may hinder our ability to market our products in those states or localities. Manufacturers are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. We may be required to incur significant costs to comply with such laws and regulations now or in the future. Such laws or regulations may have a material adverse effect upon our ability to do business.

Exports of our products are regulated by the FDA and are covered by the Export Amendment of 1996, which greatly expanded the export of approved and unapproved United States medical devices. However, some foreign countries require manufacturers to provide an FDA certificate for products for export ("CPE") which requires the device manufacturer to certify to the FDA that the product has been granted 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 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. In addition, many of the Ophthalmologic diseases that we treat, especially AMD, affect individuals primarily covered by Medicare. 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.

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. For example, during July 2000, the CMS advised that claims for reimbursement for certain AMD procedures that use our OcuLight SLx laser system would not be reimbursed by CMS. As a result, since July 2000, sales of the OcuLight SLx laser system have dropped significantly. In September 2000, CMS changed its position and advised that claims for reimbursement for two of the AMD procedures can be submitted for reimbursement with coverage and payment to be determined by the local medical carriers at their discretion. Sales of the OcuLight SLx continue, albeit at a lower level, because the OcuLight SLx can also be used for other retinal procedures that are reimbursable by the CMS. Furthermore, since CMS advisories are for domestic third party CMS payers, they are not likely to affect international sales. We believe domestic sales of the OcuLight SLx laser system will continue at these lower levels until more 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. As an example, to date, Medicare reimbursement to ophthalmologists performing TTT procedures to treat wet AMD is available in 17 states. We believe that more medical carriers will reimburse for these procedures when the procedures are further validated by randomized clinical studies. We are supporting a randomized clinical trial (TTT4CNV) which may further validate the position TTT will have in the overall treatment regimen of AMD.

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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. 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 January 1, 2005, we had a total of 108 full-time employees, including 52 in operations, 28 in sales and marketing, 17 in research and development and 11 in finance and administration. We also employ, from time to time, a number of temporary and part-time employees as well as consultants on a contract basis. At January 1, 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.

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, as soon as reasonably practicable after such reports are electronically filed with the Securities and Exchange Commission and are also available on the SEC's website at www.sec.gov.

Our website and the information contained therein or connected thereto are not intended to be incorporated into this Annual Report on Form 10-K.

Item 2. Properties

Our operating facility is 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 this facility, and in September 2003, we entered into a lease amendment for this facility in Mountain View. The original lease term of this facility,

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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

The Company is not subject to any material legal proceedings as of the date of this report.

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

	<u>High</u>	<u>Low</u>
Fiscal 2005		
First Quarter (through March 16, 2005)	\$ 6.19	\$ 4.21
Fiscal 2004		
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 2003		
First Quarter	\$ 4.14	\$ 2.75
Second Quarter	4.23	3.18
Third Quarter	5.15	2.98
Fourth Quarter	6.10	3.86

Fiscal 2004

On March 16, 2005, the closing price on the NASDAQ National Market for our common stock was \$5.52 per share. As of March 16, 2005, 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.

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As of January 1, 2005, we had three equity compensation plans. These plans are the 1995 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 January 1, 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	1,823,392	\$ 5.18	454,251
Equity compensation plans not approved by security holders	0	0	0
Total	1,823,392	\$ 5.18	454,251

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

The following selected consolidated financial data as of January 1, 2005 and January 3, 2004, and for the years ended January 1, 2005, January 3, 2004 and December 28, 2002, 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 29, 2001 and December 30, 2000 and the consolidated balance sheet data as of December 28, 2002, December 29, 2001 and December 30, 2000 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."

	<u>Fiscal Year 2004</u>	<u>Fiscal Year 2003</u>	<u>Fiscal Year 2002</u>	<u>Fiscal Year 2001</u>	<u>Fiscal Year 2000</u>
Consolidated Statement of Operations Data:					
Sales	\$ 32,810	\$ 31,699	\$ 30,634	\$ 27,275	\$ 32,838
Cost of sales	17,922	17,628	17,046	14,205	14,506
Gross profit	14,888	14,071	13,588	13,070	18,332
Operating expenses:					
Research and development	4,509	4,032	4,315	4,808	5,265
Selling, general and administrative	11,455	10,087	9,454	10,251	10,747
Total operating expenses	15,964	14,119	13,769	15,059	16,012
Income (loss) from operations	(1,076)	(48)	(181)	(1,989)	2,320
Interest and other income, net	319	212	122	426	569
Income (loss) before provision for income taxes	(757)	164	(59)	(1,563)	2,889
Benefit from (provision for) income taxes	355	207	209	962	(809)
Income (loss) from continuing operations	(402)	371	150	(601)	2,080
Income (loss) from operations of discontinued Laser Research segment (net of applicable income tax benefit (provision) of \$0, \$0, \$0, \$124 and \$(131) respectively)	—	—	—	(204)	336
Loss on disposal of Laser Research segment (net of applicable income tax benefit of \$0, \$0, \$0, \$315 and \$0 respectively)	—	—	—	(468)	—
Net income (loss)	<u>\$ (402)</u>	<u>\$ 371</u>	<u>\$ 150</u>	<u>\$ (1,273)</u>	<u>\$ 2,416</u>
Basic net income (loss) per share:					
Continuing operations	\$ (0.06)	\$ 0.05	\$ 0.02	\$ (0.09)	\$ 0.31
Discontinued operations	—	—	—	(0.10)	0.05
Basic net income (loss) per common share.....	<u>\$ (0.06)</u>	<u>\$ 0.05</u>	<u>\$ 0.02</u>	<u>\$ (0.19)</u>	<u>\$ 0.36</u>
Diluted net income (loss) per share:					
Continuing operations	\$ (0.06)	\$ 0.05	\$ 0.02	\$ (0.09)	\$ 0.29
Discontinued operations	—	—	—	(0.10)	0.04
Diluted net income (loss) per share	<u>\$ (0.06)</u>	<u>\$ 0.05</u>	<u>\$ 0.02</u>	<u>\$ (0.19)</u>	<u>\$ 0.33</u>
Shares used in net income (loss) per common share basic calculations					
	<u>7,200</u>	<u>6,933</u>	<u>6,870</u>	<u>6,757</u>	<u>6,637</u>
Shares used in net income (loss) per common share diluted calculations					
	<u>7,200</u>	<u>7,072</u>	<u>6,928</u>	<u>6,757</u>	<u>7,285</u>

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	January 1, 2005	January 3, 2004	December 28, 2002	December 29, 2001	December 30, 2000
Consolidated Balance Sheet Data:					
Cash, cash equivalents and available-for-sale securities	\$ 18,028	\$ 16,292	\$ 11,542	\$ 9,102	\$ 12,994
Working capital	25,342	28,462	28,072	26,374	27,005
Total assets	39,093	35,839	34,272	33,788	35,025
Total stockholders' equity	31,783	30,834	30,198	29,833	30,500

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

Overview

IRIDEX Corporation is a leading worldwide provider of semiconductor-based laser systems 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 68 independent distributors into 107 countries. Total sales in 2004, 2003, and 2002 were \$32.8 million, \$31.7 million, and \$30.6 million respectively.

Our revenues arise primarily from the sale of our IRIS Medical OcuLight Systems, IQ810, VariLite, DioLite 532 and Apex 800 systems, delivery devices, disposables and, to a lesser extent, 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. We also produce the Millennium Endolase module which is sold exclusively to Bausch & Lomb and incorporated into their Millennium Microsurgical System. We believe that future growth in laser unit sales will be derived from growth in sales of peripheral delivery devices, disposable EndoProbes and service revenue, our new product introductions, replacement of old laser instruments and technology and from the adoption of new less invasive procedures (MIP), such as Transpupillary Thermotherapy.

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 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.

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

	Fiscal Year Ended 2004	Fiscal Year Ended 2003	Fiscal Year Ended 2002
Sales	100%	100.0%	100.0%
Cost of sales	54.6	55.6	55.6
Gross profit	45.4	44.4	44.4
Operating expenses:			
Research and development	13.7	12.7	14.1
Sales, general and administrative	35.0	31.8	30.9
Total operating expenses	48.7	44.5	45.0
Operating loss	(3.3)	(0.1)	(0.6)
Other income, net	1.0	0.7	0.4
Income (loss) before benefit for income taxes	(2.3)	0.6	(0.2)
Benefit from income taxes	1.1	0.7	0.7
Net income (loss)	(1.2%)	1.3%	0.5%

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 January 1, 2005		Year Ended January 3, 2004		Year Ended December 28, 2002	
	Amount	Percentage of total sales	Amount	Percentage of total sales	Amount	Percentage of total sales
Domestic	\$ 19,894	60.6%	\$ 20,072	63.3%	\$ 19,564	63.9%
International	\$ 12,916	39.4%	11,627	36.7%	11,070	36.1%
Total	\$ 32,810	100%	\$ 31,699	100.0%	\$ 30,634	100.0%
Ophthalmology:						
Domestic	\$ 16,443	50.1%	\$ 15,724	49.6%	\$ 14,326	46.8%
International	\$ 11,310	34.5%	10,436	32.9%	9,843	32.1%
Total	\$ 27,753	84.6%	\$ 26,160	82.5%	\$ 24,169	78.9%
Dermatology:						
Domestic	\$ 3,451	10.5%	\$ 4,348	13.7%	\$ 5,238	17.1%
International	\$ 1,606	4.9%	1,191	3.8%	1,227	4.0%
Total	\$ 5,057	15.4%	\$ 5,539	17.5%	\$ 6,465	21.1%

Combined Ophthalmology and Dermatology Sales

In 2004, sales increased by 3.5% to \$32.8 million from \$31.7 million in 2003. Domestic sales, which represented 60.6% of total 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 a \$0.9 million decrease in domestic dermatology revenue offset by a \$0.7 million increase in domestic ophthalmology revenue. International sales, which were 39.4% of total 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.

In 2003, sales increased by 3.5% to \$31.7 million from \$30.6 million in 2002. Domestic sales, which represented 63.3% of total sales, increased by 2.6% to \$20.1 million in 2003 from \$19.6 million in 2002. The increase in domestic sales was a result of \$1.4 million increase in domestic ophthalmology revenue offset by \$0.9 million in decreased domestic dermatology revenue. International sales, which were 36.7% of total sales, increased by 5.0% to \$11.6 million in 2003 from \$11.1 million in 2002. International ophthalmology sales increased in 2003 by \$0.5 million while international dermatology sales remained at \$1.2 million.

Ophthalmology Sales

In 2004, ophthalmology sales increased 6.1% to \$27.8 million from \$26.2 million in 2003. Domestic ophthalmology sales increased 4.6% to \$16.4 million in 2004 from \$15.7 million in 2003. Domestic ophthalmology sales increased during this period mainly as a result of \$0.5 million in increased service revenue, \$0.3 million in increased unit sales of delivery devices offset by \$0.1 million in decreased unit sales of laser consoles. International ophthalmology sales increased 8.4% to \$11.3 million from \$10.4 million. The increase in international sales was due primarily to a \$0.5 million increase in unit sales of laser consoles, \$0.2 million in increased service revenue and \$0.2 million in increased delivery device unit sales.

In 2003, ophthalmology sales increased 8.2% to \$26.2 million from \$24.2 million in 2002. Domestic ophthalmology sales increased 9.8% to \$15.7 million in 2003 from \$14.3 million in 2002. Domestic ophthalmology sales increased during this period mainly as a result of \$0.5 million in increased unit sales of delivery devices, \$0.5 million in increased service revenue and \$0.4 million in increased unit sales of laser consoles. International ophthalmology sales increased 6.0% to \$10.4 million. The increase in international sales was due primarily to a \$0.1 million increase in unit sales of laser consoles, \$0.2 million in increased service revenue, \$0.2 million in increased average selling prices and \$0.1 million in increased unit sales of delivery devices.

Dermatology Sales

Dermatology sales decreased 8.7% in 2004 to \$5.1 million from \$5.5 million in 2003. Domestic dermatology sales decreased 20.6% to \$3.5 million in 2004 from \$4.3 million in 2003. The decrease in domestic dermatology sales was due primarily to \$1.3 million in decreased unit sales of the DioLite laser and Apex hair removal lasers and \$0.1 million in decreased average selling prices offset by \$0.5 million in sales of the new VariLite laser. International dermatology sales increased 34.9% to \$1.6 million in 2004 from \$1.2

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million in 2003 due to a \$0.3 million increase in unit sales of laser consoles and a \$0.1 million increase in service revenue.

Dermatology sales decreased 14.3% in 2003 to \$5.5 million from \$6.5 million in 2002. Domestic dermatology sales decreased 17.0% to \$4.3 million in 2003 from \$5.2 million in 2002. The decrease in domestic dermatology sales was due primarily to a \$0.8 million in decreased unit sales of the DioLite and Apex laser, \$0.3 million in decreased average selling prices, offset in part, by \$0.2 million in increased service revenue. International dermatology sales remained constant at \$1.2 million for 2003 and 2002.

Gross Profit. Gross profit was \$14.9 million in 2004, \$14.1 million in 2003 and \$13.6 million in 2002. Gross profit represented 45.4% of sales in 2004 and 44.4% of sales in 2003 and 2002 respectively. The total 1.0% increase in gross profit as a percentage of revenue in 2004 was due primarily 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 partially associated with the Company's recent introduction of new products and a decrease of 0.1% associated with average selling prices. In 2003, a slight increase of 0.3% in direct inventory costs was offset by the same level of decrease in overhead spending.

Gross profit was \$14.1 million in 2003, \$13.6 million in 2002 and \$13.1 million in 2001. Gross profit represented 44.4% of sales in 2003 and 2002 and 47.9% in 2001. In 2003, a slight increase of 0.3% in direct inventory costs was offset by the same level of decrease in overhead spending.

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."

Research and Development. Research and development expenses increased by \$0.5 million or 11.8% in 2004 to \$4.5 million from \$4.0 million in 2003. The increase in 2004, in absolute dollars, consisted of a \$0.6 million increase in project spending related mainly to spending on two products released in 2004, the IQ810 and VariLite. Research and development expenses decreased by 6.6% in 2003 to \$4.0 million from \$4.3 million in 2002. The decrease in 2003, in absolute dollars, consisted of \$0.2 million in reduced personnel spending related to the reduction in force in June 2002, \$0.1 million in decreased clinical spending and \$0.1 million in reduced occupancy spending associated with renegotiation of a lease, offset by \$0.1 million in increased project spending. These expenses were 13.7% of sales in 2004, 12.7% of sales in 2003 and 14.1% of sales in 2002. The increase, as a percentage of net sales, from 2003 to 2004 was attributable to the increase in research and development expense relative to the increase in the level of sales. The decrease in research and development expenses in 2003, as a percentage of sales, was due to the decline in expenses in absolute dollars and an increase in the level of sales. For fiscal 2005, we expect research and development expense to increase slightly as a result of development spending for new products and product improvement initiatives.

Sales, General and Administrative. Sales, general and administrative expense increased by 13.6% in 2004 to \$11.5 million from \$10.1 million in 2003. Sales, general and administrative expense increased by 6.7% in 2003 to \$10.1 million from \$9.5 million in 2002. The increase in selling, general and administrative expenses in 2004 was driven primarily by a one-time \$1.0 million charge to establish a reserve for unpaid sales taxes and interest, \$0.1 million in associated sales tax consulting fees and a \$0.3 million increase in the allowance for doubtful accounts. The reserve for sales tax resulted from the completion of a comprehensive review of our sales tax practices. Historically we had been collecting and remitting sales tax in only those states where we believed we had nexus. Based on the independent review, we are now collecting and remitting sales tax from customers in additional states and are in the process on entering into voluntary settlement agreements with certain states. The Company chose not to retroactively collect this sales tax from our customers. The increase in selling, general and administrative expense in 2003 was driven primarily by \$0.4 million in increased non-commission related selling activities and \$0.2 million in

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administrative spending associated primarily with increased consulting and insurance costs. These expenses were 34.9% of sales in 2004, 31.8% of sales in 2003 and 30.9% of sales in 2002. The increase, as a percentage of net sales, from 2003 to 2004, was attributable to the increase in sales, general and administrative expense relative to the increase in the level of sales. For 2005 we expect sales, general and administrative expense, in absolute dollars, to decrease. Although spending in connection with Sarbanes-Oxley compliance initiatives will increase, overall spending for 2005 will decrease as it will not include the one-time charge of \$1.0 million for sales tax.

Interest income, other income (expense), net. Other income, net consists primarily of interest income. Interest income was \$249,000, \$159,000 and \$151,000 in 2004, 2003 and 2002, respectively. This income was primarily from interest earned on available-for-sale securities. Interest income increased in 2004 over 2003 mainly as a result of higher average cash balances during 2004.

Income Taxes. In 2004, our effective rate was a benefit of 47%. In 2003 and 2002, our effective rate was a benefit of 127% and 360%, respectively. The tax rate for 2004 was higher 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 and 2002 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 and 2002.

Liquidity and Capital Resources

At January 1, 2005, our primary sources of liquidity included cash and cash equivalents of \$10.4 million and available-for-sale securities of \$7.6 million, for a total of \$18.0 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 2005. As of January 1, 2005, no borrowings were outstanding under this credit facility. We expect to renew the line of credit in October 2005 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.

Net cash generated by operations in 2004 totaled \$0.8 million as compared with \$5.1 million generated by operations in 2003 and \$2.5 million by operations in 2002. In 2004, sources of cash included an increase in net accrued expenses and accounts payable of \$2.0 million, depreciation of \$0.4 million, an increase in deferred revenue of \$0.3 million and a decrease in prepaid expense of \$0.1 million. Uses of cash in 2004 included a net increase in accounts receivable of \$0.8 million, an increase in the deferred tax asset of \$0.6 million, a net loss of \$0.4 million and an increase in net inventory of \$0.2 million. The increase in net accrued expenses related mainly to a reserve and associated consulting fees for sales tax totalling \$1.2 million, increased payroll accruals of \$0.2 million due to the timing of payroll and other increases in accrued royalties and accrued warranty which individually were less significant. The increase in accounts receivable was due to mainly to the timing of sales in the fourth quarter of 2004. Inventory increased in 2004 primarily because of inventory purchases associated with new product introductions. In 2003, sources of cash included decreases in net inventories of \$2.0 million, decreases in net accounts receivable of \$1.4 million, depreciation of \$0.7 million, an increase in accrued expenses of \$0.6 million, an increase in accounts payable of \$0.4 million, and net income of \$0.4 million. Uses of cash in 2003 included an increase in the deferred tax asset of \$0.2 million and decreases in prepaid expenses of \$0.2 million. The decrease in inventory was due mainly

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to an ongoing inventory reduction program. The decrease in accounts receivable was due to increased collection efforts. The increase in accrued expenses consisted mainly of \$0.3 million for income tax payable and \$0.2 million for deferred revenue. In 2002, sources of cash included decreases in net inventories of \$1.8 million, depreciation of \$0.9 million, increases in accrued expenses of \$0.6 million, decreases in prepaid expenses of \$0.3 million and net income of \$0.2 million. Uses of cash in 2002 included decreases in accounts payable of \$0.5 million, increases in net accounts receivable of \$0.5 million and an increase in the deferred tax asset of \$0.3 million. The decrease in inventory and accounts payable was due mainly to implementation of an inventory reduction program. The increase in accrued expenses consisted mainly of \$0.4 million for income tax payable, \$0.1 million for an increase in accrued warranty and \$0.1 million for an accrued liability. The decrease in prepaid expenses consisted primarily of \$0.4 million for tax receivable.

In 2004, we used \$2.3 million in cash for investing activities. We used \$4.0 million in cash for investing activities in 2003. In 2002, we generated \$1.8 million of cash from investing activities. Net cash provided by or used in investing activities was primarily due to the purchase and proceeds of available-for-sale securities and the acquisition of fixed assets.

Net cash provided by financing activities during 2004, 2003 and 2002 was \$1.4 million, \$0.2 million and \$0.2 million, respectively, which consisted primarily of issuance of stock in connection with our employee stock programs.

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 employee stock programs. No shares of our common stock from the open market were purchased during 2004, 2003 and 2002. As of January 1, 2005, we have repurchased 103,000 shares of common stock under this program.

Critical Accounting Policies

The preparation of our 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. Deferred revenue relating to warranty contracts is recognized on a straight line basis over the period of the applicable warranty contract. Cost is recognized as incurred. Up-front fees received in connection with product sales are deferred and recognized over the associated product shipments.

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 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, 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 change 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, current economic trends 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 2004. 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, current economic trends and changes in our customer payment terms when evaluating the adequacy of the allowance for doubtful accounts. Our accounts receivable balance was \$7.4 million, net of allowance for doubtful accounts of \$0.5 million as of January 1, 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 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

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 January 1, 2005(in thousands):

Payments Due by Period

<u>Contractual Obligations</u>	<u>Total</u>	<u>2005</u>	<u>2006</u>	<u>2007</u>	<u>2008</u>	<u>2009</u>	<u>2010 and thereafter</u>
Operating Leases	\$ 1,709	\$ 390	\$ 402	\$ 416	\$ 429	\$ 72	\$ 0
Unconditional Purchase Obligations*	\$ 10,050	\$ 8,814	\$ 1,236	\$ 0	\$ 0	\$ 0	\$ 0
Total Contractual Cash Obligations	\$ 11,759	\$ 9,204	\$ 1,638	\$ 416	\$ 429	\$ 0	\$ 0

* Contractual purchase obligations have varying cancellation terms.

Recent Accounting Pronouncements

In November 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 151, Inventory Costs, an amendment of ARB No. 43, Chapter 4. SFAS No. 151 clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs and wasted material. SFAS No. 151 is effective for inventory costs incurred during fiscal years beginning in the second quarter of fiscal 2006. We do not believe the adoption of SFAS No. 151 will have a material effect on our consolidated financial position, results of operations or cash flows.

In December 2004, the FASB issued SFAS No. 123R, Share-Based Payment, which replaced SFAS No. 123 and superseded APB 25. SFAS No. 123R addresses the accounting for share-based payment transactions in which a company receives employee services in exchange for either equity instruments of the company or liabilities that are based on the fair value of the Company's equity instruments or that may be settled by the issuance of such equity instruments. Under SFAS No. 123R, companies will no longer be able to account for share-based compensation transactions using the intrinsic method in accordance with APB 25 but will be required to account for such transactions using a fair-value method and recognize the expense in the consolidated statement of earnings. SFAS No. 123R is effective beginning in the third quarter of fiscal 2005 and allows, but does not require, companies to restate the full fiscal year of adoption to reflect the impact of expensing share-based payments under SFAS No. 123R. The Company has not yet determined which fair-value method and transitional provision it will follow. The pro forma impact on the Company's financial statements of applying Black-Scholes option valuation method of accounting for stock options is disclosed in the Notes to Consolidated Financial Statements.

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 semiconductor-based photocoagulator medical laser systems to the ophthalmic market. We also market visible and infrared light semiconductor-based photocoagulator medical laser systems to the dermatology market. We believe that continued and increased sales, if any, of these medical laser systems is dependent upon a number of factors including the following:

- Product performance, features, ease of use, scalability and durability;
- 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;
- Willingness of ophthalmologists and dermatologists to convert to semiconductor-based or infrared laser systems from alternative technologies; and
- Level of reimbursement for treatments administered with our products.

In addition, we derive a meaningful portion of our revenues from the sale of delivery devices. Our ability to increase revenues from the sale of delivery devices will depend primarily upon the features, 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 laser competitors in ophthalmology are Lumenis Ltd., Carl Zeiss, Inc., Alcon, Quantel, Laserex and Nidek, 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) and Macugen (Eyeteck) compete rigorously with traditional laser procedures. Our principal competitors in dermatology are Palomar Technologies, Laserscope, Candela Corporation, Lumenis Ltd. and Cutera, Inc. 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.

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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. In September and October 2004 we introduced two new laser products, the IQ810 in ophthalmology and the VariLite in dermatology. In May 2004, we introduced a new type of illuminating Endoprobe. In June 2003 we began shipment of two new products; a 50 micron slit lamp adaptor and a 25 gauge single-use Endoprobe. In October 2002, we announced the introduction of a number of new products, specifically the OcuLight Symphony multi-wavelength laser delivery system, an expanded EndoProbe product line and a 5 mm Large Spot Slit Lamp Adapter. We also announced the Millennium Endolase module in 2002, which we manufacture to be included in Bausch & Lomb's Millennium Microsurgical System. Successful commercialization of these and other new products and new applications will require that we effectively transfer production processes from research and development to manufacturing and effectively coordinate with our suppliers. In addition, we must successfully sell and achieve market acceptance of new products and applications and enhanced versions of existing products. The extent of, and rate at which, market acceptance and penetration are achieved by future products is a function of many variables, which include, among other things, price, safety, efficacy, reliability, marketing and sales efforts, the development of new applications for these products, the availability of third-party reimbursement of procedures using our new products, the existence of competing products and general economic conditions affecting purchasing patterns. Our ability to market and sell new products may also be subject to government regulation, including approval or clearance by the 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 2004, 2003 and 2002 sales of our ophthalmology products were \$27.8 million, \$26.2 million and \$24.2 million or 84.6%, 82.5% and 78.9%, 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 as we continue to introduce new ophthalmology products, such as the IQ810 Laser System.

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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 2004, 2003 and 2002, our international sales were \$12.9 million, \$11.6 million and \$11.1 million, or 39.4%, 36.7% and 36.1%, respectively, of total sales. We anticipate that international sales will continue to account for a significant portion of our revenues 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:

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.

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. As of January 1, 2005 our direct sales force consisted of 13 employees with 3 additional open positions and we maintained relationships with 68 independent distributors internationally selling our products into 107 countries. We generally grant our distributors exclusive territories for the sale of our products in specified countries. The amount and timing of resources dedicated by our distributors to the sales of our products is not within our control. Our international sales are entirely dependent on the efforts of these third parties. If any distributor breaches 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.

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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. We have supported several clinical trials, including, for example, the TTT4CNV clinical trial. The TTT4CNV clinical trial is a physician initiated multi-center, prospective, double-masked, placebo-controlled, randomized trial conducted at 22 centers in the United States. This is a clinical trial performed within the FDA cleared indications of the OcuLight SLx and is being 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 AMD compared to a randomized control, which should reflect the natural history of the disease. In June 2003, we announced the publication of two additional clinical studies, which also support the effectiveness of TTT for the treatment of wet age-related macular degeneration. Both studies were prospective, non-randomized, non-masked case series that were performed using our OcuLight SLx laser and Large Spot Size Slit Lamp Adapter. 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, did not result in a significant beneficial effect relative to sham and that further subgroup analysis would be conducted. Since that time, interim 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. Any impact on laser sales related to these trial results may take a number of years. If the future results of any clinical trial regarding our products fails to demonstrate improved outcomes of treatments using our products, our ability to generate revenues from new products or new applications using our products would be adversely affected.

We Face Manufacturing Risks. The manufacture of our infrared and visible light photocoagulators and the related delivery devices 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 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.

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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:

- 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;
- 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 development costs.

In addition to these factors, our quarterly results have been, and are expected to continue to be, affected by seasonal factors.

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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.

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 development 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 Bausch & Lomb will result in further sales of our Millennium Endolase module. We also collaborated with Miravant Medical Technologies, a maker of photodynamic drugs, on a device that emits a laser beam to activate a photodynamic drug developed by Miravant for the treatment of wet AMD. In January 2002, Miravant announced that the top line results of their Phase III clinical trial indicated that PHOTREX the photodynamic drug developed, did not meet the primary efficacy endpoint in the study population. As we could not be assured that PHOTREX would be timely or successfully pursued through clinical trials by Miravant, we charged to expense in the fourth quarter of 2001, \$0.3 million of inventory related to the OcuLight 664, the laser used by Miravant in the Phase III clinical trials. Miravant has since received an approvable letter from the FDA for PHOTREX with conditions for final marketing approval which includes a request for an additional confirmatory clinical trial. We are the exclusive provider of the OcuLight 664 activation laser used in this application. Successful commercialization of this product will depend, among other things, on the results of the confirmatory clinical trial, acceptance of this product and Miravant's ability to successfully market and sell this therapy. The failure 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 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. 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.

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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 (QSRs) 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.

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.

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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 four 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.

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.

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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.

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 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 infrared laser systems 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.

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.

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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 development 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 development activities, manufacturing, our corporate headquarters and other critical business operations are located near major earthquake faults in Mountain View, California. Any such loss at any of our facilities could disrupt our operations, delay production, shipments and revenue and result in large expense to repair and replace our facilities.

We 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.

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. We receive only limited attention by securities analysts and may experience an imbalance between supply and demand for our common stock 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.

Changes in Accounting Rules. We prepare our financial statements in conformity with accounting principles generally accepted in the United States of America. These principles are subject to interpretation by the Securities and Exchange Commission, or the SEC, and various bodies formed to interpret and create appropriate accounting policies. A change in these policies can have a significant effect on our reported results and may even retroactively affect previously reported transactions.

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Changes in Accounting Rules for Stock-Based Compensation May Adversely Affect Our Operating Results, Our Stock Price and Our Competitiveness in the Employee Marketplace. We have a history of using employee stock options and other stock-based compensation to hire, motivate and retain our workforce. In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 123R, "Share-Based Payment," which will require us, starting in the second half of 2005, to measure compensation costs for all stock-based compensation (including stock options and our employee stock purchase plan) at fair value and to recognize these costs as expenses in our statements of operations. The recognition of these expenses in our statements of operations will result in lower earnings per share, which could negatively impact our future stock price. In addition, if we reduced or alter our use of stock-based compensation to minimize the recognition of these expenses, our ability to recruit, motivate and retain employees may be impaired, which could put us at a competitive disadvantage in the employee marketplace.

Compliance With Internal Controls Evaluations and Attestation Requirements. Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we will be required, beginning in fiscal 2006, to perform an evaluation of our internal controls over financial reporting and have our auditor publicly attest to such evaluation. We have prepared an internal plan of action for compliance, which includes a timeline and scheduled activities, although as of the date of this filing we have not yet prepared the evaluation. Compliance with these requirements is expected to be expensive and time-consuming. If we fail to timely complete this evaluation, or if our registered independent public accounting firm cannot timely attest to our evaluation, we could be subject to regulatory scrutiny and a loss of public confidence in our internal controls. In addition, any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our reporting obligations.

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. We have no long-term debt as of January 1, 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 or interest reset dates do not extend beyond fiscal year 2005 and the interest rates are primarily fixed.

Qualitative Disclosures

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

- 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.

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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 January 1, 2005 and January 3, 2004 and the consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the three years in the period ended January 1, 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 January 1, 2005 and January 3, 2004, and the results of their operations and their cash flows for each of the three years in the period ended January 1, 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
April 1, 2005

IRIDEX Corporation

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

	January 1, 2005	January 3, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 10,381	\$ 10,541
Available-for-sale securities	3,323	5,751
Accounts receivable, net of allowance for doubtful accounts of \$496 in 2004 and \$120 in 2003	7,404	6,548
Inventories, net	8,922	8,721
Prepays and other current assets	814	934
Short term deferred income taxes	1,808	972
Total current assets	32,652	33,467
Long term portion of available-for-sale securities	4,324	—
Property and equipment, net	852	850
Deferred income taxes	1,265	1,522
Total assets	<u>\$ 39,093</u>	<u>\$ 35,839</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,233	\$ 1,029
Accrued expenses	5,167	3,380
Deferred revenue	910	596
Total liabilities	7,310	5,005
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: 7,308,857 shares in 2004 and 6,987,033 shares in 2003	74	70
Additional paid-in capital	25,281	23,900
Accumulated other comprehensive loss	(35)	(1)
Treasury stock, at cost	(430)	(430)
Retained earnings	6,893	7,295
Total stockholders' equity	31,783	30,834
Total liabilities and stockholders' equity	<u>\$ 39,093</u>	<u>\$ 35,839</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 January 1, 2005	Year Ended January 3, 2004	Year Ended December 28, 2002
Sales	\$ 32,810	\$ 31,699	\$ 30,634
Cost of sales	17,922	17,628	17,046
Gross profit	14,888	14,071	13,588
Operating expenses:			
Research and development	4,509	4,032	4,315
Sales, general and administrative	11,455	10,087	9,454
Total operating expenses	15,964	14,119	13,769
Loss from operations	(1,076)	(48)	(181)
Interest income	249	159	151
Other income (expense), net	70	53	(29)
Income (loss) before income taxes	(757)	164	(59)
Benefit from income taxes	355	207	209
Net income (loss)	\$ (402)	\$ 371	\$ 150
Basic net income (loss) per common share	\$ (0.06)	\$ 0.05	\$ 0.02
Diluted net income (loss) per common share	\$ (0.06)	\$ 0.05	\$ 0.02
Shares used in net income (loss) per common share basic calculations	7,200	6,933	6,870
Shares used in net income (loss) per common share diluted calculations	7,200	7,072	6,928

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 29, 2001	6,815,672	\$ 69	\$ 23,417	\$ (430)	\$ 3	\$ 6,774	\$ 29,833
Issuance of Common Stock under Stock Option Plan	36,930		78				78
Issuance of Common Stock under Employee Stock Purchase Plan	53,396	1	126				127
Tax Benefit of Employee Stock Option Plan			10				10
Net income						150	150
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(losses) on available-for-sale securities					(34)		(34)
Net loss						(402)	(402)
Balances, January 1, 2005	<u>7,308,857</u>	<u>\$ 74</u>	<u>\$ 25,281</u>	<u>\$ (430)</u>	<u>\$ (35)</u>	<u>\$ 6,893</u>	<u>\$ 31,783</u>

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

IRIDEX Corporation

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended January 1, 2005	Year Ended January 3, 2004	Year Ended December 28, 2002
Cash flows from operating activities:			
Net income (loss)	\$ (402)	\$ 371	\$ 150
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation and amortization	384	703	869
Provision for doubtful accounts	376	(142)	(56)
Provision for inventories	694	(63)	125
Deferred income taxes	(579)	(235)	(333)
Changes in assets and liabilities:			
Accounts receivable	(1,232)	1,631	(426)
Inventories	(895)	2,067	1,712
Prepays and other current assets	120	(175)	359
Accounts payable	204	372	(519)
Accrued expenses	1,787	356	574
Deferred revenue	314	203	64
Net cash provided by operating activities	<u>771</u>	<u>5,088</u>	<u>2,519</u>
Cash flows from investing activities:			
Purchases of available-for-sale securities	(7,681)	(5,755)	(2,356)
Proceeds from maturity of available-for-sale securities	5,751	2,356	4,489
Acquisition of property and equipment	(386)	(603)	(284)
Net cash provided by (used in) investing activities	<u>(2,316)</u>	<u>(4,002)</u>	<u>1,849</u>
Cash flows from financing activities:			
Issuance of common stock under stock purchase and option plans	1,385	269	205
Net cash provided by financing activities	<u>1,385</u>	<u>269</u>	<u>205</u>
Net increase (decrease) in cash and cash equivalents	(160)	1,355	4,573
Cash and cash equivalents, beginning of year	<u>10,541</u>	<u>9,186</u>	<u>4,613</u>
Cash and cash equivalents, end of year	<u>\$ 10,381</u>	<u>\$ 10,541</u>	<u>\$ 9,186</u>
Supplemental disclosure of cash flow information:			
Cash paid during the year for:			
Income taxes	\$ 25	\$ 138	\$ 8

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

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

	Year Ended January 1, 2005	Year Ended January 3, 2004	Year Ended December 28, 2002
Net income (loss)	\$ (402)	\$ 371	\$ 150
Other comprehensive loss:			
Changes in unrealized losses on available-for-sale securities, net	<u>(34)</u>	<u>(4)</u>	<u>—</u>
Comprehensive income (loss)	<u>\$ (436)</u>	<u>\$ 367</u>	<u>\$ 150</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 semiconductor-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 which are subject to minimal credit risk.

Available-for-Sale Securities

All marketable securities as of January 1, 2005 and January 3, 2004 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, current economic trends 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

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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. Our accounts receivable balance was \$7.4 million, net of allowance for doubtful accounts of \$0.5 million as of January 1, 2005.

Inventories

Inventories are stated at the lower of cost or market. 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 balances. 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 shorter of the lease duration or 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.

Deferred Revenue

Deferred 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 ending January 3, 2004 and January 1, 2005 follows (in thousands):

Balance, December 28, 2002	\$ 393
Additions to deferral	670
Revenue recognized	<u>(467)</u>
Balance, January 3, 2004	596
Additions to deferral	1,146
Revenue recognized	<u>(832)</u>
Balance, January 1, 2005	<u>\$ 910</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 revenues. A reconciliation of the changes in the Company's warranty liability for the years ending January 3, 2004 and January 1, 2005 follows (in thousands):

Balance, December 28, 2002	\$ 796
Accruals for warranties issued during the year	361
Settlements made in kind during the year	<u>(356)</u>
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	<u>\$ 933</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 2004, 2003 and 2002 were \$218,000, \$311,000 and \$242,000, 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. 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.

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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):

	Year Ended January 1, 2005	Year Ended January 3, 2004	Year Ended December 28, 2002
Net income (loss), as reported	\$ (402)	\$ 371	\$ 150
Add: Total stock based compensation expense determined under fair value based method for all awards	(560)	(534)	(438)
Pro forma net loss	<u>\$ (962)</u>	<u>\$ (163)</u>	<u>\$ (288)</u>
Basic net income (loss) per share:			
As reported	<u>\$ (0.06)</u>	<u>\$ 0.05</u>	<u>\$ 0.02</u>
Pro forma	<u>\$ (0.13)</u>	<u>\$ (0.02)</u>	<u>\$ (0.04)</u>
Diluted net income (loss) per share:			
As reported	<u>\$ (0.06)</u>	<u>\$ 0.05</u>	<u>\$ 0.02</u>
Pro forma	<u>\$ (0.13)</u>	<u>\$ (0.02)</u>	<u>\$ (0.04)</u>

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:

	2004		2003		2002	
	Group A	Group B	Group A	Group B	Group A	Group B
Risk-free Interest Rates	3.50%	3.50%	3.30%	3.30%	4.38%	4.38%
Expected Life from Date of Vesting	5 yrs.	2 yrs.	4 yrs.	2 yrs.	4 yrs.	2 yrs.
Volatility	0.88	0.88	0.88	0.88	0.84	0.84
Dividend Yield	—	—	—	—	—	—

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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 2004, 2003 and 2002 was \$4.89, \$2.96 and \$2.48, 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 2004, 2003 and 2002.

We have 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 2004, 2003 and 2002:

	2004	2003	2002
Risk-free Interest Rates	2.56%	1.45%	2.01%
Expected Life	0.5 year	0.5 year	0.5 year
Volatility	0.84	0.86	0.85
Dividend Yield	—	—	—

The weighted average grant-date fair value per share of those purchase rights granted in 2004, 2003 and 2002 was \$1.37, \$1.01 and \$1.31, respectively.

Concentration of Credit Risk and Other Risks and Uncertainties

Our 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.

We market our 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, we have not experienced any significant losses related to individual customers or group of customers in any particular geographic area. For the years ended January 1, 2005, January 3, 2004 and December 28, 2002 no customer accounted for greater than 10% of revenue. As of January 1, 2005 and January 3, 2004 no customers accounted for more than 10% of accounts receivable.

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

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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

Our fiscal year covers a 52 or 53 week period and ends on the Saturday nearest December 31. Fiscal year 2004 and 2002 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 6.

Recent Accounting Pronouncements

In November 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 151, Inventory Costs, an amendment of ARB No. 43, Chapter 4. SFAS No. 151 clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs and wasted material. SFAS No. 151 is effective for inventory costs incurred during fiscal years beginning in the second quarter of fiscal 2006. We do not believe the adoption of SFAS No. 151 will have a material effect on our consolidated financial position, results of operations or cash flows.

In December 2004, the FASB issued SFAS No. 123R, Share-Based Payment, which replaced SFAS No. 123 and superseded APB 25. SFAS No. 123R addresses the accounting for share-based payment transactions in which a company receives employee services in exchange for either equity instruments of the company or liabilities that are based on the fair value of the Company's equity instruments or that may be settled by the issuance of such equity instruments. Under SFAS No. 123R, companies will no longer be able to account for share-based compensation transactions using the intrinsic method in accordance with APB 25 but will be required to account for such transactions using a fair-value method and recognize the expense in the consolidated statement of earnings. SFAS No. 123R is effective beginning in the second quarter of fiscal 2006 and allows, but does not require, companies to restate the full fiscal year of adoption to reflect the impact of expensing share-based payments under SFAS No. 123R. The Company has not yet determined which fair-value method and transitional provision it will follow. The pro forma impact on the Company's

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financial statements of applying Black-Scholes option valuation method of accounting for stock options is disclosed in the Notes to Consolidated Financial Statements.

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 January 1, 2005, short term available-for-sale securities consisted of the following:				
Corporate notes	\$ 3,345	\$ (22)	\$ 3,323	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	\$ 4,312	\$ (12)	\$ 4,324	2/06 – 5/06
Total	<u>\$ 4,312</u>	<u>\$ (12)</u>	<u>\$ 4,324</u>	

As of January 3, 2004, short term available-for-sale securities consisted of the following:

Corporate notes	\$ 4,752	\$ (1)	\$ 4,751	2/04 - 10/04
Government agencies	1,000	—	1,000	2/04 - 4/04
Total	<u>\$ 5,752</u>	<u>\$ (1)</u>	<u>\$ 5,751</u>	

There were no realized capital gains or losses recognized in 2004, 2003 and 2002.

	<u>January 1, 2005</u>	<u>January 3, 2004</u>
Inventories:		
Raw materials and work in process	\$ 5,460	\$ 4,426
Finished goods	3,462	4,295
Total inventories	<u>\$ 8,922</u>	<u>\$ 8,721</u>
Property and Equipment:		
Equipment	\$ 4,264	\$ 3,887
Leasehold improvements	1,903	1,894
Less: accumulated depreciation and amortization	(5,315)	(4,931)
Property and equipment, net	<u>\$ 852</u>	<u>\$ 850</u>
Accrued Expenses:		
Accrued payroll, vacation and related expenses	\$ 1,100	\$ 1,009
Accrued warranty	933	801
Income taxes payable	783	733
Sales and use tax payable	1,277	122
Other accrued expenses	1,074	715
Total accrued expenses	<u>\$ 5,167</u>	<u>\$ 3,380</u>

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4. Bank Borrowings

We have 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 (5.25% at January 1, 2005). 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 January 1, 2005.

5. Commitments and Contingencies

Lease Agreements

We lease our operating facilities under a noncancelable operating lease. 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 until 2014 at a base monthly rental amount to be negotiated at the time of the renewal. Rent expense, net of sublease income, totaled \$403,000, \$606,000 and \$642,000 for the years ended January 1, 2005, January 3, 2004 and December 28, 2002 respectively.

Future minimum lease payments under current operating leases at January 1, 2005 are summarized as follows (*in thousands*):

<u>Fiscal Year</u>	<u>Operating Lease Payments</u>
2005	390
2006	402
2007	416
2008	429
2009	72
	<u>\$ 1,709</u>

License Agreements

The Company is obligated to pay royalties equivalent to 5% and 7.5% of sales on certain products under license agreements. Royalty expense was \$80,000, \$93,000 and \$105,000 for the years ended January 1, 2005, January 3, 2004 and December 28, 2002, respectively.

Contingencies

From time to time, the Company may be engaged in certain administrative proceedings, incidental to its normal business activities. Management believes that liabilities resulting from such proceedings, or claims which are pending or known to be threatened, are adequately covered by liability insurance and will not have a material adverse effect on the Company's financial position or results of operations.

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

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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 January 1, 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 2002, 2003 and 2004, no shares of Common Stock were repurchased. As of January 1, 2005 we have repurchased 103,000 shares of common stock.

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") 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 and stock purchase rights ("SPRs"). The exercise price of incentive stock options and SPRs 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

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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 January 3, 2004 and December 28, 2002 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 options become exercisable in full and shall be exercisable for 30 days after written notice to the holder of the event causing the change in control.

Unless terminated sooner, the Director Plan will terminate in 2005. The Board has authority to amend or terminate the Director Plan, provided no such amendment may impair the rights of any optionee without the optionee's consent.

1995 Employee Stock Purchase Plan

Our 1995 Employee Stock Purchase Plan (the "Purchase Plan") was adopted by the Board of Directors in October 1995. The total number of shares of common stock reserved for issuance under the Purchase Plan at January 1, 2005 was 55,450. The Purchase Plan permits eligible employees (including officers and employee directors) 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 1,000 shares of Common Stock in any six-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. The Purchase Plan will terminate in 2005, unless terminated sooner by the Board of Directors.

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Information with respect to activity under these option plans are set forth below (in thousands):

	Outstanding Options			
	Shares Available for Grant	Number of Shares	Aggregate Price	Weighted Average Exercise Price
Balances, December 29, 2001	183,298	1,656,817	\$ 8,831	\$ 5.34
Additional shares reserved	300,000	—	—	—
Options granted	(229,400)	229,400	858	3.74
Options exercised		(36,930)	(78)	2.08
Options cancelled	(2,575)			
Options terminated	<u>148,424</u>	<u>(148,424)</u>	<u>(924)</u>	6.23
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	<u>39,114</u>	<u>(39,114)</u>	<u>(189)</u>	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	<u>100,789</u>	<u>(100,789)</u>	<u>(701)</u>	6.95
Balances, January 1, 2005	<u>454,251</u>	<u>1,823,392</u>	<u>\$ 9,428</u>	\$ 5.18

The following table summarizes information with respect to stock options outstanding at January 1, 2005:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding at 1/01/05	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable at 1/01/05	Weighted Average Exercise Price
\$1.00 - \$3.30	231,110	7.18	\$ 2.95	104,576	\$ 2.57
\$3.41 - \$3.71	317,699	7.30	3.59	199,782	3.62
\$3.75 - \$4.00	342,989	3.14	3.99	325,791	4.00
\$4.01 - \$4.74	188,999	6.84	4.27	119,543	4.19
\$4.88 - \$5.50	212,991	6.04	5.22	139,448	5.15
\$5.65 - \$7.25	198,279	7.95	6.65	64,804	6.61
\$7.38 - \$9.00	236,075	4.49	8.60	225,257	8.66
\$9.06 - \$12.19	80,250	5.73	9.73	67,875	9.85
\$12.75 - \$12.75	11,250	5.50	12.75	11,250	12.75
\$14.88 - \$14.88	<u>3,750</u>	1.49	14.88	<u>3,750</u>	14.88
\$1.00 — \$14.88	<u>1,823,392</u>	5.92	\$ 5.18	<u>1,262,076</u>	5.36

At January 3, 2004 and December 28, 2002 options to purchase 1,354,937 and 1,184,805 shares of common stock were exercisable at a weighted average exercise price of \$ 5.29 and \$5.22, respectively.

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7. Employee Benefit Plan

We have 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 \$88,000 in 2004, \$89,000 in 2003 and \$98,000 in 2002.

8. Income Taxes

The provision for income taxes includes:

	Year Ended January 1, 2005	Year Ended January, 2004	Year Ended December 28, 2002
Current:			
Federal	\$ 212	\$ 19	\$ 121
State	14	9	5
	<u>226</u>	<u>28</u>	<u>126</u>
Deferred:			
Federal	(519)	(148)	(231)
State	(62)	(87)	(104)
	<u>(581)</u>	<u>(235)</u>	<u>(335)</u>
Income tax benefit	<u>\$ (355)</u>	<u>\$ (207)</u>	<u>\$ (209)</u>

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

	Year Ended January 1, 2005	Year Ended January 3, 2004	Year Ended December 28, 2002
Income tax provision (benefit) at statutory rate	34%	34%	(34%)
State income taxes, net of federal benefit	8%	6%	(6%)
Tax exempt interest	0%	0%	0%
Nondeductible permanent differences	-5%	19%	56%
Research and development credits	12%	(164%)	(377%)
Other	-2%	(22%)	1%
Effective tax rate	<u>47%</u>	<u>(127%)</u>	<u>(360%)</u>

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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):

	<u>January 1, 2005</u>	<u>January 3, 2004</u>
Fixed assets	\$ 640	\$ 610
Accrued liabilities	1,039	492
Allowance for excess and obsolete inventories	514	413
Research credit	626	852
State tax	1	1
Allowance for doubtful accounts	184	47
Other	69	79
Net deferred tax asset	<u>\$ 3,073</u>	<u>\$ 2,494</u>

9. Major Customers and Business Segments

We operate in two reportable segments: the ophthalmology medical device segment and the dermatology medical device segment. In both segments, we develop, manufacture and market medical devices. Our revenues arise from the sale of consoles, delivery devices, disposables and service and support activities.

In the years ended January 1, 2005, January 3, 2004, and December 28, 2002, no customer individually accounted for more than 10% of our revenue.

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

	<u>January 1, 2005</u>	<u>January 3, 2004</u>	<u>December 28, 2002</u>
United States	\$ 19,894	\$ 20,072	\$ 19,564
Europe	\$ 6,498	5,297	5,429
Rest of Americas	\$ 631	1,000	833
Asia/Pacific Rim	\$ 5,787	5,330	4,808
	<u>\$ 32,810</u>	<u>\$ 31,699</u>	<u>\$ 30,634</u>

Revenues are attributed to countries based on location of customers.

In the years ended January 1, 2005, January 3, 2004 and December 28, 2002, no country individually accounted for more than 10% of our sales, except for the United States, which accounted for 60.6% of sales in 2004, 63.3% in 2003 and 63.9% in 2002.

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Information on reportable segments for the three years ended January 1, 2005, January 3, 2004, and December 28, 2002 is as follows:

	Year Ended January 1, 2005		
	Ophthalmology Medical Devices	Dermatology Medical Devices	Total
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
Income (loss) from operations			\$ (1,076)

	Year Ended January 3, 2004		
	Ophthalmology Medical Devices	Dermatology Medical Devices	Total
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
Income (loss) from operations			\$ (48)

	Year Ended December 28, 2002		
	Ophthalmology Medical Devices	Dermatology Medical Devices	Total
Sales	\$ 24,169	\$ 6,465	\$ 30,634
Direct cost of goods sold	\$ 7,917	\$ 2,844	\$ 10,761
Direct gross margin	\$ 16,252	\$ 3,621	\$ 19,873
Total unallocated indirect costs			\$ 20,054
Income (loss) from operations			\$ (181)

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.

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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 January 1, 2005	Year Ended January 3, 2004	Year Ended December 28, 2002
Net income (loss)	\$ (402)	\$ 371	\$ 150
Denominator — Net income (loss) per common share Weighted average common stock outstanding	7,200	6,933	6,870
Effect of dilutive securities Weighted average common stock options	—	139	58
Total weighted average stock and options outstanding	<u>7,200</u>	<u>7,072</u>	<u>6,928</u>
Net income (loss) per common share	<u>\$ (0.06)</u>	<u>\$ 0.05</u>	<u>\$ 0.02</u>
Diluted net income (loss) per common share	<u>\$ (0.06)</u>	<u>\$ 0.05</u>	<u>\$ 0.02</u>

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. In 2003 and 2002, there were 791,406 and 1,296,391, outstanding options to purchase shares, respectively, at weighted average exercise prices of \$6.99 and \$5.97 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. 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 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
Year Ended January 3, 2004				
Sales	\$ 7,226	\$ 7,435	\$ 8,267	\$ 8,771
Gross profit	\$ 3,238	\$ 3,120	\$ 3,589	\$ 4,124
Net income (loss)	\$ (82)	\$ (299)	\$ 261	\$ 491
Net income (loss) per common share	\$ (0.01)	\$ (0.04)	\$ 0.04	\$ 0.07
Diluted net income (loss) per common share	\$ (0.01)	\$ (0.04)	\$ 0.04	\$ 0.07
The fourth quarter of 2003 includes 14 weeks				

Item 9. Changes in And Disagreements with Accountants On Accounting and Financial Disclosure

Not applicable.

Item 9A. Controls and Procedures.

Disclosure controls and procedures

Our management evaluated, with the participation of our Chief Executive Officer and our Chief Financial Officer, the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

Changes in internal control over financial reporting.

There was no change in our internal control over financial reporting that occurred during the period covered by this Annual Report on Form 10-K that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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 2005 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 1, 2005.

Item 10. Directors and Executive Officers of the Registrant

Information regarding our directors required by this item is incorporated herein by reference to our Proxy Statement. The information concerning our current executive officers, delinquent filers, our code of business conduct and ethics, members of our Audit Committee, the identification of the Audit Committee Financial Expert and stockholder nominators of directors is also incorporated 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 Registered Public Accounting Firm" 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	43
Consolidated Balance Sheets as of January 1, 2005 and January 3, 2004	44
Consolidated Statements of Operations for the years ended January 1, 2005, January 3, 2004 and December 28, 2002	45
Consolidated Statements of Stockholders' Equity for the years ended anuary 1, 2005, January 3, 2004 and December 28, 2002	46
Consolidated Statements of Cash Flows for the years ended January 1, 2005, January 3, 2004 and December 28, 2002	47
Consolidated Statements of Comprehensive Income (Loss) for the years ended January 1, 2005, January 3, 2004 and December 28, 2002	48
Notes to Consolidated Financial Statements	49
2. Financial Statement Schedule	
The following financial statement schedule of IRIDEX Corporation for the years ended January 1, 2005, January 3, 2004 and December 28, 2002 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	68

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(3)‡	1995 Employee Stock Purchase Plan, as amended and form of agreement thereunder.
10.3(3)‡	1995 Director Option Plan and form of agreement thereunder.
10.4(1)‡	1995 Profit Sharing Plan.
10.5(1)	Third Restated Registration Rights Agreement dated as of October 27, 1995 by and among Registrant and certain individuals and entities named therein.
10.6(4)	Lease Agreement dated December 6, 1996 by and between Zappettini Investment Co. and the Registrant, as amended.

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<u>Exhibits</u>	<u>Exhibit Title</u>
10.7(3)‡	1998 Stock Option Plan, as amended.
10.8(5)‡	2005 Employee Stock Purchase Plan and form of agreement thereunder.
10.9(6)‡	2005 Bonus Plan.
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.
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 and 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 the Registrant's Report on Form 10-Q for the quarter ended October 3, 1998.
 - (3) Incorporated by reference to the Exhibits in the Registrant's Registration Statement on Form S-8 which was filed on August 3, 2004 which was filed April 30, 1998.
 - (4) Incorporated by reference to the Exhibits in the Registrant's Report on Form 10-Q for the quarter ended September 27, 2003.
 - (5) Incorporated by reference to the Exhibits in the Registrant's Proxy Statement for the Registrant's 2004 Annual Meeting of Stockholders.
 - (6) Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on March 22, 2005.

‡ Indicates a management Compensatory Plan, contract or arrangement.

Trademark Acknowledgments

IRIDEX, the IRIDEX logo, IRIS Medical, OcuLight, 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, Varispot 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 December 28, 2002:				
Allowance for doubtful accounts receivable	\$ 318	\$ (56)	\$ —	\$ 262
Provision for inventory	\$ 981	\$ 125	\$ —	\$ 1,106
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	\$ —	\$ 496
Provision for inventory	\$ 1,043	\$ 694	\$ —	\$ 1,737

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Mountain View, State of California, on 1st day of April, 2005.

IRIDEX CORPORATION

By: /s/ Theodore A. Boutacoff
Theodore A. Boutacoff
President, Chief Executive Officer, and Director

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

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

<u>/s/ Theodore A. Boutacoff</u> (Theodore A. Boutacoff)	<i>President, Chief Executive Officer, and Director (Principal Executive Officer)</i>	April 1, 2005
<u>/s/ Larry Tannenbaum</u> (Larry Tannenbaum)	<i>Chief Financial Officer and Vice President, Administration (Principal Financial and Accounting Officer)</i>	April 1, 2005
<u>/s/ James L. Donovan</u> (James L. Donovan)	<i>Vice President, Corporate Business Development and Director</i>	April 1, 2005
<u>/s/ Robert K. Anderson</u> (Robert K. Anderson)	<i>Director</i>	April 1, 2005
<u>/s/ Sanford Fitch</u> (Sanford Fitch)	<i>Director</i>	April 1, 2005
<u>/s/Garrett A. Garrettson</u> (Garrett A. Garetson)	<i>Director</i>	April 1, 2005
<u>/s/ Joshua Makower</u> (Joshua Makower)	<i>Director</i>	April 1, 2005
<u>/s/ Donald L. Hammond</u> (Donald L. Hammond)	<i>Chairman of the Board</i>	April 1, 2005

EXHIBIT INDEX

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‡ Indicates a management compensatory plan, contract or arrangement.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Forms S-8 (No. 333-117885, 333-32161, 333-57573, 333-860191, 333-45736, 333-67480, 333-97541 and 333-10770) of IRIDEX Corporation of our report dated April 1, 2005 relating to the financial statements and financial statement schedule, which appears in this Form 10-K.

PriceWaterhouseCoopers LLP
San Jose, CA
April 1, 2005

**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, Theodore A. Boutacoff, certify that:

1. I have reviewed this Annual Report on Form 10-K of IRIDEX Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material facts or omit to state a material facts necessary to make the statements 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 officer 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 report is being prepared;
 - b) Evaluated the effectiveness of the registrant's disclosure controls 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; and
5. The registrant's other certifying officer 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 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: April 1, 2005

By: /s/ THEODORE A. BOUTACOFF

Name: Theodore A. Boutacoff

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

**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 Annual 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 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 officer 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 report is being prepared;
 - b. Evaluated the effectiveness of the registrant's disclosure controls 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; and
5. The registrant's other certifying officer 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 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: April 1, 2005

By: /s/ LARRY TANNENBAUM

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

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND 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, Theodore A. Boutacoff, 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 January 1, 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: April 1, 2005

By: /s/ THEODORE A. BOUTACOFF
Name: Theodore A. Boutacoff
Title: President and Chief Executive Officer (Principal Executive Officer)

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 January 1, 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: April 1, 2005

By: /s/ LARRY TANNENBAUM
Name: Larry Tannenbaum
Title: Chief Financial Officer and Vice President,
Administration
(Principal Financial and Accounting Officer)