

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 3, 2004

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 \$ 11,096,234, as of June 28, 2003, 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, 2003, Registrant had 7,097,099 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain parts of the Proxy Statement for the Registrant's 2004 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 sometimes as aesthetics). Our products are sold in the United States predominantly through a direct sales force and internationally through 66 independent distributors into 107 countries. Total product sales in 2003, 2002 and 2001 were \$31.7 million, \$30.6 million and \$27.3 million respectively, which generated a net income (loss) from continuing operations for those corresponding years of \$371,000, \$150,000 and (\$601,000).

Our ophthalmology products are used in the treatment of serious eye diseases, including the three leading causes of irreversible blindness, age-related macular degeneration (AMD), diabetic retinopathy and glaucoma. The current family of OcuLight 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 OcuLight Symphony (Laser Delivery System), OcuLight SL, OcuLight SLx, OcuLight GL and OcuLight GLx laser photocoagulation systems. Our ophthalmology products contributed \$26.2 million, \$24.1 million and \$20.9 million to our total revenues in 2003, 2002 and 2001, respectively. Our dermatology products treat skin conditions, primarily vascular and pigmented lesions and remove unwanted hair. Our dermatology laser systems are the DioLite 532 and the Apex 800 systems. Our dermatology products are primarily used in the practitioner’s office and contributed \$5.5 million, \$6.5 million and \$6.4 million to our total revenues in 2003, 2002 and 2001, 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. We believe that our semiconductor-based systems were among the first

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to be developed and since our first shipment in 1990, more than 6,300 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 2001, we introduced the Apex 800, a high powered infrared laser for hair removal for the dermatology market. In October 2002, we introduced the OcuLight Symphony Laser Delivery System which combines the clinical versatility and convenience of infrared and visible photocoagulation consoles into one delivery device. We also introduced an expanded EndoProbe product line and a 5 millimeter Large Spot Slit Lamp Adapter. In December 2002, we commenced shipment of the Millennium Endolase module, which we manufacture to be included in Bausch & Lomb's Millennium Microsurgical System. In 2003, we introduced a 50 micron spot slit lamp adapter, the smallest spot size diameter available on IRIDEX slit lamp adapters. In addition, in 2003 and the first quarter of 2004, we introduced four additions to our Endoprobe product line. 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 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 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 and diabetic retinopathy. Our products are currently being used in

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multiple studies in the United States and internationally to demonstrate the clinical benefits of MIP protocols. For example, our OcuLight SLx laser is being 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 March 2003, we announced that the Executive Committee for the TTT4CNV clinical trial, studying TTT as a therapy for the treatment of wet AMD, accepted the recommendations of the independent Data and Safety Monitoring Committee that adequate patient enrollment in the study had been attained. We believe that new applications increase laser usage and may ultimately increase the size of the market for laser photocoagulators. 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 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. 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, 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, 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 \$75,000, and

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consist of laser consoles and specialized delivery devices and our line of disposable products has an average sales price of approximately \$120.

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

Infrared Photocoagulator Consoles. These OcuLight photocoagulator consoles used by ophthalmologists are available in two infrared (810nm) output power ranges: the OcuLight SL at 2 Watts and the OcuLight SLx at 3 Watts. Each console weighs 14 pounds, has dimensions of 4"H x 12"W x 12"D, draws a maximum of 60 Watts of wall power, and requires no external air or water cooling. We also manufacture the Apex 800 infrared laser product designed to be used in dermatology. The Apex 800 console weighs 27 pounds, has dimensions of 6"H x 12"W x 17"D, draws 700 Watts of wall power and has a closed loop integrated water cooling system. We believe that the smaller overall sizes, lower weights and low power requirements to operate represent distinct advantages over competing products.

Visible (or Green) Photocoagulator Consoles. Our OcuLight GL and OcuLight GLx semiconductor-based photocoagulator consoles used in ophthalmology deliver visible (532nm) laser light. The OcuLight GLx has increased power and delivery device capability. Our visible laser light dermatology product, the DioLite 532, is also based on semiconductor-based technology. The OcuLight GL/GLx/DioLite consoles weigh 15 pounds, have dimensions of 6"H x 12"W x 12"D, draw a maximum of 300 Watts of wall power and require no external air or water cooling. In December 2002, we commenced shipment of the Millennium Endolase module, which is sold exclusively to Bausch & Lomb for use in their Millennium Microsurgical System. It integrates 532nm photocoagulator capability into Bausch & Lomb's array of microsurgical capabilities. The Millennium Endolase module is compatible with the IRIDEX EndoProbe handpieces and Laser Indirect Ophthalmoscope.

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.

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 and to be in procedures to treat peripheral retinal disorders, particularly in infants or adults requiring treatment in the supine position. This product can be used in both diagnosis and treatment procedures at the point-of-care.

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

Operating Microscope Adapter. These adapters allow the physician to utilize a standard operating microscope in both diagnosis and laser treatment procedures. These devices are similar to slit lamp adapters, except that they are oriented horizontally and therefore can be used to deliver retinal photocoagulation to a supine patient.

EndoProbe. The EndoProbe 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, illuminating and aspirating styles. In 2003 and the first quarter of 2004, we introduced four additions to our EndoProbe product line, including straight and angled illuminating laser probes, a 25 gauge probe and aspirating probe.

G-Probe. The G-Probe is used in procedures to treat medically and surgically uncontrolled glaucoma, in many instances replacing cyclocryotherapy, or freezing of the eye. The G-Probe's non-invasive procedure takes approximately ten minutes, is done to an anesthetized eye in the doctor's office and results in less pain and fewer adverse side effects than cyclocryotherapy. The G-Probe is a sterile disposable product.

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.

ScanLite Scanner. The ScanLite is a computer pattern generator with integrated controls designed to enhance the capabilities of the DioLite 532 laser system. 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.

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

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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.

Condition	Procedure	Console	Delivery Devices
<i>Ophthalmology Treatments:</i>			
Age-related Macular Degeneration	Retinal Photocoagulation	Infrared & Visible	Slit Lamp Adapter
Diabetic Retinopathy			
Macular Edema	Grid Retinal Photocoagulation	Infrared & Visible	Slit Lamp Adapter & Operating Microscope Adapter,
	Focal Retinal Photocoagulation	Visible	Slit Lamp Adapter
Proliferative	Pan-Retinal Photocoagulation	Infrared & Visible	Slit Lamp Adapter, Operating Microscope Adapter, Laser Indirect Ophthalmoscope, EndoProbe
<i>Glaucoma</i>			
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, DioPexy Probe
	Transscleral Retinal Photocoagulation	Infrared	
Retinopathy of Prematurity	Retinal Photocoagulation	Infrared	Laser Indirect Ophthalmoscope
Ocular Tumors	Retinal Photocoagulation	Infrared	Slit Lamp Adapter, Operating Microscope Adapter, Laser Indirect Ophthalmoscope
<i>Dermatology Treatments:</i>			
Vascular Lesions	Selective Photothermolysis	Visible	DioLite Handpiece
Pigmented Lesions	Selective Photothermolysis	Visible	DioLite Handpiece
Hair Removal	Selective Photothermolysis	Infrared	Cold Tip Handpiece, Varispot Handpiece

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

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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 \$4.0 million, \$4.3 million and \$4.8 million in 2003, 2002 and 2001, respectively. We expect to continue to devote a significant portion 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 and a multi-center randomized trial called the TTT4CNV Trial, which we are supporting, completed the required level of enrollment in March 2003. The independent Data and Safety Monitoring Committee (DSMC) for the TTT4CNV clinical trial meets semiannually to evaluate the status of the study.

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.

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

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

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

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 2003, 2002 or 2001. 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 internationally who are each potential customers. Additionally, we estimate that there are approximately 4,900 and 18,000 hospitals in the United States and internationally, respectively, as well as approximately 2,300 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, warranty returns and other administrative functions. Our technical support engineers provide customers with answers to technical and product-related questions. We maintain an "around-the-clock" telephone service line to service our customers. If a problem with a product cannot be diagnosed and resolved by telephone, a replacement unit is shipped overnight to any domestic customer and by the most rapid delivery means available to any international customer, and the problem unit is returned to us. The small size and rugged design of our products allows for economical shipment and quick response to customers almost anywhere in the world.

Sales and Marketing

We market our products in the United States predominantly through our direct sales force. As of January 3, 2004, our direct sales force consisted of 9 employees, with 5 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.

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International product sales represented 36.7%, 36.1% and 41.3% of our sales in 2003, 2002 and 2001, 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 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 3, 2004, we had a total of 53 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.

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We rely on third parties to manufacture substantially all of the components used in our products, although we assemble critical subassemblies and the final product at our facility in Mountain View, California. Some of these suppliers and manufacturers are sole source. We have some long-term or volume purchase agreements with our suppliers and currently purchase most components on a purchase order basis. These components may not be available in the quantities required, on reasonable terms, or at all. Financial or other difficulties faced by our suppliers or significant changes in demand for these components or materials could limit their availability. Any failures by such third parties to adequately perform may delay the submission of products for regulatory approval, impair our ability to deliver products on a timely basis or otherwise impair our competitive position. See Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Factors That May Affect Future Results—We Face Risks of Manufacturing and We Depend on Key Manufacturers and Suppliers.”

International regulatory bodies often establish varying product standards, packaging requirements, labeling requirements, tariff regulations, duties and tax requirements. As a result of our sales in Europe, we are required to have all products “CE” marked, an international symbol affixed to all products demonstrating compliance to the European Medical Device Directive and all applicable standards. In July 1998, we received CE mark under Annex II guidelines, the most stringent path to CE certification. With Annex II CE certification, we have demonstrated our ability to both understand and comply with all applicable European standards. This allows us to CE mark any product upon our internal verification of compliance to all applicable European standards. Currently, all released products are CE marked. Continued certification is based on successful review of the process by our European Registrar during its annual audit. Any loss of certification would have a material adverse effect on our business, results of operations and financial condition. See Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Factors That May Affect Future Results-We Are Subject to Government Regulation.”

Competition

Competition in the market for devices used for ophthalmic and dermatology treatment procedures is intense and is expected to increase. This market is also characterized by rapid technological innovation and change, and our products could become obsolete as a result of future innovations. Our competitive position depends on a number of factors including product performance, characteristics and functionality, ease of use, scalability, durability and cost. In addition to other companies that manufacture photocoagulators and dermatological devices, we compete with pharmaceutical solutions, other technologies and other surgical techniques available in both the dermatologic and ophthalmic markets. Our principal competitors in ophthalmology are Lumenis Ltd., Carl Zeiss Meditec AG, Alcon Inc., Quantel and Nidek, Inc. All of these companies currently offer a competitive, semiconductor-based laser system for ophthalmology. Our principal competitors in dermatology are Laserscope, Candela Corporation, Palomar Technologies, Lumenis Ltd., and Cutera Inc. (formerly known as Altus Medical 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, such as Visudyne which is marketed by QLT, Inc./Novartis Pharma AG, 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 14 United States patents and two 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 eight 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, such as our Apex 800 system, modifications or enhancements that could significantly affect the safety or efficacy of the device or that constitute a major change to the intended use of the device will require new 510(k) submissions.

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

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used to manufacture the device. In addition, the submission must also contain the proposed labeling, advertising literature and training methods.

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

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

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

We have obtained 510(k) clearance for all of our marketed products. We have also modified aspects of our products since receiving regulatory clearance, but we believe that new 510(k) clearances are not required for these modifications. After a device receives 510(k) clearance or a PMA, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new clearance or approval. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with our determination not to seek a new 510(k) clearance or PMA, the FDA may retroactively require us to seek 510(k) clearance or premarket approval. The FDA could also require us to cease marketing and distribution and/or recall the modified device until 510(k) clearance or PMA approval is obtained. Also, in these circumstances, we may be subject to significant regulating fines or penalties.

Any products manufactured or distributed by us pursuant to FDA clearances or approvals are subject to pervasive and continuing regulation by the FDA, including record keeping requirements and reporting of adverse experiences with the use of the device. Device manufacturers are required to register their

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establishments and list their devices with the FDA and certain state agencies, and are subject to periodic inspections by the FDA and certain state agencies. The FDA Act requires devices to be manufactured to comply with applicable QSR regulations which impose certain procedural and documentation requirements upon us with respect to design, development, manufacturing and quality assurance activities. We are subject to unannounced inspections by the FDA and the Food and Drug Branch of the California Department of Health Services, or CDHS, to determine our compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of our subcontractors.

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

Exports of our products are regulated by the FDA and are covered by the Export Amendment of 1996, which greatly expanded the export of approved and unapproved United States medical devices. However, some foreign countries require manufacturers to provide an FDA certificate for products for export ("CPE") which requires the device manufacturer to certify to the FDA that the product has been granted 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. 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.

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 maintain product liability insurance with coverage limits of \$11.0 million per occurrence and an annual aggregate maximum of \$12.0 million, the coverage of our insurance policies may not be adequate. Such insurance is expensive and in the future may not be available on acceptable terms, if at all. A successful claim brought against us in excess of our insurance coverage could have a material adverse effect on our business, results of operations and financial condition. To date, we have not experienced any product liability claims which would result in payments in excess of our policy limits.

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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 3, 2004, we had a total of 106 full-time employees, including 53 in operations, 25 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 3, 2004, 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.

Item 2. Properties

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

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

Item 3. Legal Proceedings

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

	<u>High</u>	<u>Low</u>
Fiscal 2004		
First Quarter (through March 16, 2004)	\$7.46	\$4.95
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 2002		
First Quarter	\$6.05	\$4.17
Second Quarter	4.69	3.40
Third Quarter	3.92	2.31
Fourth Quarter	4.02	2.78

On March 16, 2004, the closing price on the NASDAQ National Market for our common stock was \$7.10 per share. As of March 16, 2004, there were approximately 77 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 3, 2004, 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 3, 2004:

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	2,004,283	\$4.91	395,634
Equity compensation plans not approved by security holders	0	0	0
Total	2,004,283	\$4.91	395,634

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

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

	Fiscal Year 2003	Fiscal Year 2002	Fiscal Year 2001	Fiscal Year 2000	Fiscal Year 1999
Consolidated Statement of Operations Data:					
Sales	\$31,699	\$30,634	\$27,275	\$32,838	\$26,391
Cost of sales	17,628	17,046	14,205	14,506	11,669
Gross profit	14,071	13,588	13,070	18,332	14,722
Operating expenses:					
Research and development	4,032	4,315	4,808	5,265	3,925
Selling, general and administrative	10,087	9,454	10,251	10,747	9,224
Total operating expenses	14,119	13,769	15,059	16,012	13,149
Income (loss) from operations	(48)	(181)	(1,989)	2,320	1,573
Interest and other income, net	212	122	426	569	556
Income (loss) before provision for income taxes	164	(59)	(1,563)	2,889	2,129
Benefit from (provision for) income taxes	207	209	962	(809)	(682)
Income (loss) from continuing operations	371	150	(601)	2,080	1,447
Income (loss) from operations of discontinued Laser Research segment (net of applicable income tax benefit (provision) of \$0, \$0, \$124, \$(131) and \$(80) respectively)	—	—	(204)	336	171
Loss on disposal of Laser Research segment (net of applicable income tax benefit of \$0, \$0, \$315, \$0 and \$0 respectively)	—	—	(468)	—	—
Net income (loss)	\$ 371	\$ 150	\$ (1,273)	\$ 2,416	\$ 1,618
Basic net income (loss) per share:					
Continuing operations	\$ 0.05	\$ 0.02	\$ (0.09)	\$ 0.31	\$ 0.22
Discontinued operations	—	—	(0.10)	0.05	0.03
Basic net income (loss) per common share	\$ 0.05	\$ 0.02	\$ (0.19)	\$ 0.36	\$ 0.25
Diluted net income (loss) per share:					
Continuing operations	\$ 0.05	\$ 0.02	\$ (0.09)	\$ 0.29	\$ 0.21
Discontinued operations	—	—	(0.10)	0.04	0.03
Diluted net income (loss) per share	\$ 0.05	\$ 0.02	\$ (0.19)	\$ 0.33	\$ 0.24
Shares used in net income (loss) per common share basic calculations	6,933	6,870	6,757	6,637	6,503
Shares used in net income (loss) per common share diluted calculations	7,072	6,928	6,757	7,285	6,849

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	January 3, 2004	December 28, 2002	December 29, 2001	December 30, 2000	January 1, 2000
Consolidated Balance Sheet Data:					
Cash, cash equivalents and available-for-sale securities	\$16,292	\$11,542	\$ 9,102	\$12,994	\$13,148
Working capital	28,462	28,072	26,374	27,005	23,842
Total assets	35,839	34,272	33,788	35,025	32,763
Total stockholders' equity	30,834	30,198	29,833	30,500	27,504

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 66 independent distributors into 107 countries. Total product sales in 2003, 2002, and 2001 were \$31.7 million, \$30.6 million, and \$27.3 million respectively.

Our revenues arise primarily from the sale of our IRIS Medical OcuLight Systems, 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 unit sales will be derived from growth in sales of peripheral delivery devices and service revenue, our new product introductions, replacement of old laser instruments and technology and from the adoption of new less invasive procedures using our existing products, 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.

Results of Operations

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

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	Fiscal Year Ended 2003	Fiscal Year Ended 2002	Fiscal Year Ended 2001
Sales	100.0%	100.0%	100.0%
Cost of sales	55.6	55.6	52.1
Gross profit	44.4	44.4	47.9
Operating expenses:			
Research and development	12.7	14.1	17.6
Sales, general and administrative	31.8	30.9	37.6
Total operating expenses	44.5	45.0	55.2
Operating loss from continuing operations	(0.1)	(0.6)	(7.3)
Other income, net	0.7	0.4	1.6
Income (loss) from continuing operations before provision for income taxes	0.6	(0.2)	(5.7)
Benefit from income taxes	0.7	0.7	3.5
Income (loss) from continuing operations	1.3	0.5	(2.2)
Income (loss) from discontinued operations (net of tax)	0.0	0.0	(2.5)
Net income (loss)	1.3%	0.5%	(4.7)%

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 3, 2004		Year Ended December 28, 2002		Year Ended December 29, 2001	
	Amount	Percentage of total sales	Amount	Percentage of total sales	Amount	Percentage of total sales
Domestic	\$20,072	63.3%	\$19,564	63.9%	\$16,004	58.7%
International	11,627	36.7%	11,070	36.1%	11,271	41.3%
Total	\$31,699	100.0%	\$30,634	100.0%	\$27,275	100.0%
Ophthalmology:						
Domestic	\$15,724	49.6%	\$14,326	46.8%	\$10,976	40.2%
International	10,436	32.9%	9,843	32.1%	9,946	36.5%
Total	\$26,160	82.5%	\$24,169	78.9%	\$20,922	76.7%
Dermatology:						
Domestic	\$ 4,348	13.7%	\$ 5,238	17.1%	\$ 5,028	18.4%
International	1,191	3.8%	1,227	4.0%	1,325	4.9%
Total	\$ 5,539	17.5%	\$ 6,465	21.1%	\$ 6,353	23.3%

* The year ended January 3, 2004 includes 53 weeks as compared to the years ended December 28, 2002 and December 29, 2001 which each include 52 weeks.

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Combined Ophthalmology and Dermatology Sales

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 in increased 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. We face challenges marketing and selling our products in the current difficult economic environment, both domestically and internationally, and expect to continue to face these challenges for the foreseeable future. See “-Factors That May Affect Future Results – Our Business Has Been Adversely Impacted by the Worldwide Economic Slowdown and Related Uncertainties.”

In 2002, sales increased by 12.3% to \$30.6 million from \$27.3 million in 2001 primarily as a result of a \$3.6 million increase in domestic sales which was offset by a \$0.2 million decrease in international sales. Domestic sales, which represented 63.9% of total sales, increased in 2002 by 22.2% to \$19.6 million from \$16.0 million in 2001 which reflected a \$3.4 million increase in domestic ophthalmology sales and a \$2 million increase in domestic dermatology sales. International sales, which were 36.1% of total sales, decreased in 2002 by 1.8% to \$11.1 million from \$11.3 million in 2001 due to a \$0.1 million decrease in international ophthalmology sales and a \$0.1 million decrease in international dermatology sales.

Ophthalmology 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, \$0.2 million in increased unit sales of visible lasers and \$0.2 million in increased unit sales of infrared lasers. International ophthalmology sales increased 6.0% to \$10.4 million. The increase in international sales was due primarily to a \$0.7 million increase in unit sales of visible 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 offset by a \$0.6 million decrease in unit sales of infrared laser consoles.

Ophthalmology sales increased by 15.5% to \$24.2 million in 2002 as compared to \$20.9 million in 2001. Domestic ophthalmology sales increased 30.5% to \$14.3 million. Domestic ophthalmology sales increased during this period mainly as a result of \$2.6 million in increased unit sales of visible laser consoles, including the Millennium Endolase module, \$1.2 million in increased unit sales of delivery devices and \$0.1 million in increased service revenue offset, in part, by a decrease in average selling prices of \$0.5 million. International ophthalmology sales decreased by \$0.1 million or 1.0% to \$9.8 million. The decrease in international sales was due primarily to a \$0.2 million decrease in unit sales of infrared laser consoles, which resulted from the stronger U.S. dollar in 2002, offset by a \$0.1 million increase in combined unit sales of visible laser consoles and delivery devices.

Dermatology Sales

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 \$0.7 million in decreased unit sales of the DioLite laser,

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\$0.3 million in decreased average selling prices, \$0.1 million in decreased unit sales of the Apex hair removal laser offset, in part, by \$0.2 million in increased service revenue. International dermatology sales remained constant at \$1.2 million for 2003 and 2002.

Dermatology sales increased by 1.8% to \$6.5 million in 2002 as compared to \$6.4 million in 2001. Domestic dermatology sales increased 4.2% to \$5.2 million. The increase in domestic dermatology sales was due mainly to a \$0.4 million increase in unit sales of the Apex 800 laser system, a \$0.1 million increase in unit sales of delivery devices and \$0.1 million in increased service revenue offset, in part, by a \$0.3 million decrease in unit sales of the DioLite laser and a decrease in average selling prices of \$0.1 million. International dermatology sales decreased 7.4% to \$1.2 million. Increases in international unit sales of the Apex 800 laser system of \$0.2 million and in delivery devices of \$0.2 million were offset by a \$0.5 million decrease in unit sales of the DioLite 532.

Gross Profit. 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.

Gross profit as a percentage of sales decreased in 2002 by 3.5% as compared to 2001 as a result of 1.5% for inventory related charges, 1.2% for increased warranty costs related to a change in estimate, 1.6% for lower average selling prices offset, in part, by increased gross margin of 0.4% associated with a reduction in direct inventory costs and 0.3% for increased domestic sales which have a higher gross margin.

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 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. In 2002 research and development expenses decreased to \$4.3 million from \$4.8 million in 2001. The decrease in 2002, in absolute dollars, consisted of \$0.3 million in reduced personnel spending related to a reduction in force in June 2002, \$0.3 million in reduced spending due to the completion of the Apex Hair Removal Laser system in 2001, offset, in part, by a \$0.1 million increase in clinical spending. These expenses were 12.7% of sales in 2003, 14.1% of sales in 2002 and 17.6% of sales in 2001. The decrease in research and development expenses in 2003 and 2002, as a percentage of sales, was due to the decline in expenses in absolute dollars and an increase in the level of sales. We expect to increase our research and development expenditures in absolute dollars in 2004 as we conduct additional development projects with our existing research and development staff.

Sales, General and Administrative. Sales, general and administrative expense increased by 6.7% in 2003 to \$10.1 million from \$9.5 million in 2002. In 2002, sales general and administrative expense decreased by 7.8% from \$10.3 million in 2001. The increase in selling, general and administrative expenses in 2003 was driven primarily by \$0.4 million in increased non-commission related selling activities and \$0.2 million in administrative spending associated primarily with increased consulting and insurance costs. The decrease in

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2002 consisted of reduced marketing and administrative personnel spending of \$0.2 million related, in part, to the reduction in force in June 2002, \$0.3 million in reduced spending on marketing programs, \$0.2 million in reduced insurance spending and \$0.1 million of other cost containment actions targeted at non-personnel expenses and resulting in reduced costs. These expenses were 31.8% of sales in 2003, 30.9% of sales in 2002 and 37.6% of sales in 2001. The increase, as a percentage of net sales, from 2002 to 2003, was attributable to the increase in sales, general and administrative expense relative to the increase in the level of sales. The decrease, as a percentage of net sales, from 2001 to 2002, was due to the decrease in sales, general and administrative expense in absolute dollars and an increase in sales.

Other income, net. Other income, net consists primarily of interest income. Interest income was \$159,000, \$151,000 and \$378,000 in 2003, 2002 and 2001, respectively. This income was primarily from interest earned on available-for-sale securities. Interest income increased slightly in 2003 over 2002 but decreased for both years in comparison to 2001 as a result of lower interest rates in 2003 and 2002 and overall lower average cash balances in 2002.

Income Taxes. In 2003, our effective rate was a benefit of 127% and in 2002 it was a benefit of 360%, primarily as a result, in both cases, of pretax income approaching breakeven and the level of tax credits for research and development activities relative to the loss for 2003 and 2002. Our effective tax rate for 2001 was a benefit of 62%. The tax rate for 2001 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.

Discontinued Operations. In April 2001, we discontinued our Laser Research segment. In the first quarter of 2001, we recorded a loss of \$0.9 million (net of a \$0.5 million tax benefit). In the fourth quarter of 2001, we adjusted the loss on discontinued operations to \$0.7 million (net of a \$0.4 million income tax benefit). There were no revenues, costs or expenses for the Laser Research segment in 2003, 2002 or 2001. Sales, general and administrative costs and indirect costs of manufacturing historically were not allocated to the Laser Research segment.

The Laser Research segment conducted research and development under research grants from the U.S. Federal Government and others. We discontinued our Laser Research activities to better focus available resources on our medical applications and products. The assets of the segment, primarily inventory, were fully reserved and the liabilities were fully paid. The components of the recorded loss were inventory costs of \$0.7 million, the loss on operations for the first quarter of 2001 of \$0.3 million, estimated sales return costs of \$0.2 million, estimated costs for the phase-out period of \$0.1 million and purchase order commitments of \$0.1 million offset by a tax benefit of \$0.5 million. In the fourth quarter of 2001, the accrued loss for the discontinuation of the segment was adjusted to reflect fewer than anticipated product returns.

Reduction in Force. During the quarter ended June 28, 2002, we reduced our workforce by seventeen positions or approximately 12%. For the three months ended June 28, 2002, we recorded restructuring charges totaling approximately \$150,000 that were related primarily to the severance costs associated with the headcount reduction instituted in the second quarter of 2002.

Liquidity and Capital Resources

At January 3, 2004, our primary sources of liquidity included cash and cash equivalents of \$10.5 million and available-for-sale securities of \$5.8 million, for a total of \$16.3 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 2004. As of January 3, 2004, no borrowings were outstanding under this credit facility.

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We expect to renew the line of credit in October 2004 assuming that terms continue to be acceptable. We believe that, based on current estimates, our current cash, available-for-sale securities and the credit facility will be sufficient to meet our working capital and capital expenditure requirements at least through the next twelve months. However, we believe that the level of financial resources is a significant competitive factor in our industry, and accordingly we may choose to raise additional capital through debt or equity financing prior to the end of 2004.

Net cash generated by operations in 2003 totaled \$5.1 million as compared with \$2.5 million generated in operations in 2002 and \$3.6 million used in operations in 2001. 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 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 2001, uses of cash included increases in net inventories of \$2.8 million, a net loss of \$1.3 million, increases in deferred income taxes of \$0.3 million, decreases in accrued expenses and accounts payable of \$0.6 million, decreases in net accounts receivable of \$0.1 million offset by sources of cash from operations which included depreciation of \$0.9 million, tax benefit of employee stock option plans of \$0.4 million and decreases in prepaids and other current assets of \$0.2 million. The increase in inventory was due primarily to material purchases associated with the Apex 800 which commenced shipment in July 2001. The increase in deferred income taxes was due primarily to the tax loss generated in 2001. The decrease in accrued expenses resulted primarily from a decrease in accrued payroll. The decrease in accounts payable related to a decreased level of inventory receipts at the end of the year. Prepaid and other current assets decreased due to decreases in accounts payable of \$0.2 million and to decreased prepaid spending on trade shows.

In 2003, we used \$4.0 million for investing activities. We generated \$1.8 million for investing activities in 2002. In 2001, we used \$2.0 million of cash. Net cash provided by or used in investing activities was primarily due to the sale or purchase and proceeds of available-for-sale securities and the acquisition of fixed assets.

Net cash provided by financing activities during 2003, 2002 and 2001 was \$0.2 million, \$0.2 million and \$0.2 million, respectively, which consisted primarily of issuance of stock in connection with our employee stock programs, offset in part by purchase of treasury stock of \$0.1 million in 2001.

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 2003 and 2002. In 2001, we purchased 27,000 shares of our common stock

from the open market. As of January 3, 2004, we have repurchased 103,000 shares of common stock under this program.

Critical Accounting Policies

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

Revenue Recognition

Revenue from product sales is recognized upon receipt of a purchase order and product shipment provided no significant obligations remain and collection of the receivables is deemed probable. 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 historical returns, current economic trends and changes in customer demand of our products when evaluating the adequacy of the sales returns allowance. Warranty costs are reflected in the income statement as a cost of revenues.

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 2003. 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 \$6.5 million, net of allowance for doubtful accounts of \$0.1 million as of January 3, 2004.

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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.

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.

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 3, 2004(in thousands):

	Payments Due by Period						
	Total	2004	2005	2006	2007	2008	2009 and thereafter
Contractual Obligations							
Operating Leases	\$2,088	\$ 379	\$390	\$402	\$416	\$429	\$ 72
Unconditional Purchase Obligations*	\$5,726	\$5,134	\$592	\$ 0	\$ 0	\$ 0	\$ 0
Total Contractual Cash Obligations	\$7,814	\$5,513	\$982	\$402	\$416	\$429	\$ 72

*Contractual purchase obligations have varying cancellation terms.

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, clinicians, plastic surgeons and their associated opinion leaders;
- Price of our products and prices of competing products and technologies;
- Availability of competing products, technologies and alternative treatments;

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- 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 relative to the prices of competing delivery devices. The level of service revenues will depend on our quality of care, responsiveness and the willingness of our customers to request our services rather than purchase competing products or services. Any significant decline in market acceptance of our products or our revenues derived from the sales of laser consoles, delivery devices or services would have a material adverse effect on our business, results of operations and financial condition.

We Face Strong Competition in Our Markets and Expect the Level of Competition to Grow in the Foreseeable Future. Competition in the market for devices used for ophthalmic and dermatology treatment procedures is intense and is expected to increase. Our competitive position depends on a number of factors including product performance, characteristics and functionality, ease of use, scalability, durability and cost. Our principal competitors in ophthalmology are Lumenis Ltd., Carl Zeiss, Inc., Alcon, Quantel and Nidek, Inc. All of these companies currently offer a competitive semiconductor-based laser system in ophthalmology. Our principal competitors in dermatology are Laserscope, Candela Corporation, Palomar Technologies, 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, such as Visudyne which is marketed by QLT, Inc./Novartis Pharma AG, other technologies and other surgical techniques. Some medical companies, academic and research institutions, or others, may develop new technologies or therapies that are more effective in treating conditions targeted by us or are less expensive than our current or future products. Any such developments could have a material adverse effect on our business, financial condition and results of operations.

Our Future Success Depends on Our Ability to Develop and Successfully Introduce New Products and New Applications. Our future success is dependent upon, among other factors, our ability to develop, obtain regulatory approval or clearance of, manufacture and market new products. 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. These variables include 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

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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.

Our Business Has Been Adversely Impacted By the Worldwide Economic Slowdown and Related Uncertainties. The overall weak economic conditions worldwide have resulted in reduced demand for some of our products, particularly demand for our dermatology products. Political and social turmoil in various parts of the world or terrorist acts may adversely impact global economic conditions. These political, social and economic conditions and related economic uncertainties make it difficult for us, our customers and our distributors to forecast orders and sales of our products and, accordingly, plan future business activities. This level of uncertainty strongly challenges our ability to operate profitably or grow our business. If economic or market conditions do not improve, this may have a material adverse impact on our financial position, results of operation and cash flows.

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 us or our competitors or other factors. If we are unable to offset the anticipated decrease in our average selling prices by increasing our sales volumes, our net revenues will decline. In addition, to maintain our gross margins, we must continue to reduce the manufacturing cost of our products. Further, should average unit prices of our current products decline, we must develop and introduce new products and product enhancements with higher margins. 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 Face Risks of Manufacturing. 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. We do not currently intend to utilize any external 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.

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 source. In addition, some of these suppliers are relatively small private companies that may discontinue their operations at any time. There are risks associated with the use of independent manufacturers, including the following:

- unavailability of, shortages or limitations on the ability to obtain supplies of components in the quantities that we require;
- delays in delivery or failure of suppliers to deliver critical components on the dates we require;
- failure of suppliers to manufacture components to our specifications, and potentially reduced quality; and

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- 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, requiring 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.

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 2003, 2002 and 2001, our international sales were \$11.6 million, \$11.1 million and \$11.3 million, or 36.7%, 36.1% and 41.3%, 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 risks including:

- longer accounts receivable collection periods;
- impact of recessions in economies outside of the United States;
- foreign certification requirements, including continued ability to use the “CE” mark in Europe;
- reduced or limited protections of intellectual property rights in jurisdictions outside the United States;
- potentially adverse tax consequences; and
- multiple protectionist, adverse and changing foreign governmental laws and regulations.

Any one or more of these factors stated above could have a material adverse effect on our business, financial condition or results of operations. For additional discussion about our foreign currency risks, see Item 7A, “Quantitative and Qualitative Disclosures about Market Risk.”

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 2003, 2002 and 2001 sales of our ophthalmology products were \$26.2 million, \$24.2 million and \$20.9 million or 82.5%, 78.9% and 76.7%, respectively of total sales. We

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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 50 micron slit lamp adapter and our expanded EndoProbe product line, and support clinical trials in the field of ophthalmology, including the TTT4CNV clinical trial for the treatment of wet AMD.

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 (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 TTT. The states reimbursing for TTT are Alaska, Arizona, California, Colorado, Hawaii, Iowa, Idaho, Mississippi, North Carolina, North Dakota, Nevada, Oregon, Pennsylvania, South Dakota, Tennessee, Washington and Wyoming. Domestic sales of the OcuLight SLx laser system may continue to be limited until more local medical carriers reimburse for performing such AMD procedures or until CMS advises that claims for these procedures may be submitted directly to CMS at the national level.

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 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 are currently supporting several ongoing clinical trials, including, for example, the TTT4CNV clinical trial. The TTT4CNV clinical trial is a multi-center, prospective, double-masked, placebo-controlled, randomized trial conducted at 22 centers in the United States. We believe this clinical trial is a post marketing study 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. We believe that a favorable outcome from the TTT4CNV clinical trial will increase laser sales although this process may take a number of years. In March 2003, we announced that the Executive Committee for the TTT4CNV clinical trial accepted the

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recommendations of the independent Data and Safety Monitoring Committee that an adequate number of patients were enrolled to detect a clinically relevant difference between outcomes in TTT-treated eyes and patients not being treated. 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. We cannot assure you that results from the TTT4CNV clinical trial will prove to be successful. If the future results of the TTT4CNV clinical trial or any other 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 and our business would be harmed.

Our Operating Result 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;
- 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;
- Decreases 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.

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

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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 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 3, 2004 our direct sales force consisted of 9 employees with 5 open positions and we maintained relationships with 66 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.

We Depend on Collaborative Relationships to Develop, Introduce and Market New Products, Product Enhancements and New Applications. 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. 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. 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.

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

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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 fourteen United States patents and two foreign patents on the technologies related to our products and processes. We have approximately four pending patent applications in the United States and eight 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.

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.

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

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device manufacturer must obtain market clearance through either the 510(k) premarket notification process or the lengthier premarket approval application (PMA) process. Depending upon the type, complexity and novelty of the device and the nature of the disease or disorder to be treated, the FDA process can take several years, require extensive clinical testing and result in significant expenditures. Even if regulatory approval is obtained, later discovery of previously unknown safety issues may result in restrictions on the product, including withdrawal of the product from the market. Other countries also have extensive regulations regarding clinical trials and testing prior to new product introductions. Our failure to obtain government approvals or any delays in receipt of such approvals would have a material adverse effect on our business, results of operations and financial condition.

The FDA imposes additional regulations on manufacturers of approved medical devices. We are required to comply with the applicable Quality System regulations and our manufacturing facilities are subject to ongoing periodic inspections by the FDA and corresponding state agencies, including unannounced inspections, and must be licensed as part of the product approval process before being utilized for commercial manufacturing. Noncompliance with the applicable requirements can result in, among other things, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, withdrawal of marketing approvals, and criminal prosecution. The FDA also has the authority to request repair, replacement or refund of the cost of any device we manufacture or distribute. Any of these actions by the FDA would materially and adversely affect our ability to continue operating our business and the results of our operations.

In addition, we are also subject to varying product standards, packaging requirements, labeling requirements, tariff regulations, duties and tax requirements. As a result of our sales in Europe, we are required to have all products “CE” marked, an international symbol affixed to all products demonstrating compliance with the European Medical Device Directive and all applicable standards. While currently all of our released products are CE marked, continued certification is based on 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.

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

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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.

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 \$11.0 million per occurrence and an annual aggregate maximum of \$12.0 million, our coverage from our insurance policies may not be adequate. Product liability insurance is expensive. We might not be able to obtain product liability insurance in the future on acceptable terms or in sufficient amounts to protect us, if at all. A successful claim brought against us in excess of our insurance coverage could have a material adverse effect on our business, results of operations and financial condition.

If We Fail to 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.

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

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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 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.

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 3, 2004.

The fair value of our investment portfolio or related income would not be significantly impacted by changes in interest rates since the marketable securities maturities do not extend beyond fiscal year 2004 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.

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.

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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 3, 2004 and December 28, 2002 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 3, 2004, 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 Auditors

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 3, 2004 and December 29, 2002, and the results of their operations and their cash flows for each of the three years in the period ended January 3, 2004 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 the financial statement schedule based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America, which 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 2, 2004

IRIDEX Corporation

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

	January 3, 2004	December 28, 2002
ASSETS		
Current assets:		
Cash and cash equivalents	\$10,541	\$ 9,186
Available-for-sale securities	5,751	2,356
Accounts receivable, net of allowance for doubtful accounts of \$120 in 2003 and \$262 in 2002	6,548	8,037
Inventories, net	8,721	10,725
Prepays and other current assets	934	759
Current deferred income taxes	972	1,083
Total current assets	33,467	32,146
Property and equipment, net	850	950
Deferred income taxes	1,522	1,176
Total assets	<u>\$35,839</u>	<u>\$34,272</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,029	\$ 657
Accrued expenses	3,380	3,024
Deferred revenue	596	393
Total liabilities	<u>5,005</u>	<u>4,074</u>
Commitments and contingencies (Note 5).		
Stockholders' Equity		
Convertible Preferred Stock, \$.01 par value:		
Authorized: 2,000,000 shares;		
Issued and outstanding: none	—	—
Common Stock, \$.01 par value:		
Authorized: 30,000,000 shares;		
Issued and outstanding: 6,987,033 shares in 2003 and 6,905,998 shares in 2002	70	70
Additional paid-in capital	23,900	23,631
Accumulated other comprehensive income (loss)	(1)	3
Treasury Stock, at cost	(430)	(430)
Retained earnings	7,295	6,924
Total stockholders' equity	<u>30,834</u>	<u>30,198</u>
Total liabilities and stockholders' equity	<u>\$35,839</u>	<u>\$34,272</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 3, 2004	Year Ended December 28, 2002	Year Ended December 29, 2001
Sales	\$31,699	\$30,634	\$27,275
Cost of sales	17,628	17,046	14,205
Gross profit	14,071	13,588	13,070
Operating expenses:			
Research and development	4,032	4,315	4,808
Sales, general and administrative	10,087	9,454	10,251
Total operating expenses	14,119	13,769	15,059
Loss from operations	(48)	(181)	(1,989)
Interest income	159	151	378
Other income (expense), net	53	(29)	48
Income (loss) before income taxes	164	(59)	(1,563)
Benefit from income taxes	207	209	962
Income (loss) from continuing operations	371	150	(601)
Loss from operations of discontinued Laser Research segment (net of applicable income tax benefit of \$124 in 2001)	0	0	(204)
Loss on disposal of Laser Research segment, (net of applicable income tax benefit of \$315 in 2001)	0	0	(468)
Net income (loss)	\$ 371	\$ 150	\$ (1,273)
Basic net income (loss) per share:			
Continuing operations	\$ 0.05	\$ 0.02	\$ (0.09)
Discontinued operations	0.00	0.00	(0.10)
Basic net income (loss) per common share	\$ 0.05	\$ 0.02	\$ (0.19)
Diluted net income (loss) per share:			
Continuing operations	\$ 0.05	\$ 0.02	\$ (0.09)
Discontinued operations	0.00	0.00	(0.10)
Diluted net income (loss) per common share	\$ 0.05	\$ 0.02	\$ (0.19)
Shares used in net income (loss) per common share basic calculations	6,933	6,870	6,757
Shares used in net income (loss) per common share diluted calculations	7,072	6,928	6,757

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 30, 2000	6,700,862	\$67	\$22,691	\$(315)	\$ 10	\$ 8,047	\$30,500
Issuance of Common Stock under Stock Option Plan	74,942	1	99				100
Issuance of Common Stock under Employee Stock Purchase Plan	66,868	1	255				256
Purchase of Treasury Stock	(27,000)			(115)			(115)
Tax Benefit of Employee Stock Option Plan			372				372
Change in unrealized gains on available-for-sale securities					(7)		(7)
Net loss						(1,273)	(1,273)
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	<u>6,987,033</u>	<u>\$70</u>	<u>\$23,900</u>	<u>\$(430)</u>	<u>\$ (1)</u>	<u>\$ 7,295</u>	<u>\$30,834</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 3, 2004	Year Ended December 28, 2002	Year Ended December 29, 2001
Cash flows from operating activities:			
Net income (loss)	\$ 371	\$ 150	\$(1,273)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	703	869	859
Provision for doubtful accounts	(142)	(56)	(163)
Provision for inventories	(63)	125	322
Deferred income taxes	(220)	(333)	40
Changes in assets and liabilities:			
Accounts receivable	1,631	(426)	107
Inventories	2,067	1,712	(3,163)
Prepays and other current assets	(175)	359	206
Accounts payable	372	(519)	(232)
Accrued expenses	356	574	(521)
Deferred revenue	203	64	183
Net cash provided by (used in) operating activities	<u>5,103</u>	<u>2,519</u>	<u>(3,635)</u>
Cash flows from investing activities:			
Purchases of available-for-sale securities	(5,755)	(2,356)	(4,489)
Proceeds from maturity of available-for-sale securities	2,356	4,489	2,989
Acquisition of property and equipment	(603)	(284)	(491)
Net cash provided by (used in) investing activities	<u>(4,002)</u>	<u>1,849</u>	<u>(1,991)</u>
Cash flows from financing activities:			
Purchase of treasury stock	—	—	(115)
Issuance of common stock under stock purchase and option plans	254	205	356
Net cash provided by financing activities	<u>254</u>	<u>205</u>	<u>241</u>
Net increase (decrease) in cash and cash equivalents	1,355	4,573	(5,385)
Cash and cash equivalents, beginning of year	9,186	4,613	9,998
Cash and cash equivalents, end of year	<u>\$10,541</u>	<u>\$ 9,186</u>	<u>\$ 4,613</u>
Supplemental disclosure of cash flow information:			
Cash paid during the year for:			
Income taxes	\$ 138	\$ 8	\$ 12
Supplemental disclosure of noncash investing and financing activities:			
Change in unrealized gains (losses) on available-for-sale securities	\$ (4)	\$ —	\$ (7)

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

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

	<u>Year Ended January 3, 2004</u>	<u>Year Ended December 28, 2002</u>	<u>Year Ended December 29, 2001</u>
Net income (loss)	\$371	\$150	\$(1,273)
Other comprehensive loss:			
Changes in unrealized losses on available-for-sale securities	(4)	—	(7)
Comprehensive income (loss)	<u>\$367</u>	<u>\$150</u>	<u>\$(1,280)</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 leading 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 the accounts of our wholly-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated.

Cash and Cash Equivalents

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

Available-for-Sale Securities

All marketable securities as of January 3, 2004 and December 28, 2002 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. 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.

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.

Property and Equipment

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

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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 deemed probable. 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 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 December 28, 2002 and January 3, 2004 follows (in thousands):

Balance, December 29, 2001	\$ 329
Additions to deferral	362
Revenue recognized	(298)
Balance, December 28, 2002	393
Additions to deferral	670
Revenue recognized	(467)
Balance, January 3, 2004	\$ 596

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. We analyze historical returns, current economic trends and changes in customer demand of our products when evaluating the adequacy of the sales returns allowance. 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 year ending January 3, 2004 follows (in thousands):

Balance, December 29, 2001	\$ 582
Accruals for warranties issued during the year	463
Settlements made in kind during the year	(249)
Balance, December 28, 2002	796
Accruals for warranties issued during the year	361
Settlements made in kind during the year	(356)
Balance, January 3, 2004	\$ 801

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 2003, 2002 and 2001 were \$311,000, \$242,000 and \$408,000, respectively.

Fair Value of Financial Instruments

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

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

Income Taxes

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

Accounting for Stock-Based Compensation

The Company accounts for stock-based compensation arrangements in accordance with provisions of Accounting Principles Board Opinion (“APB”) No. 25, “Accounting for Stock Issued to Employees” and complies with the disclosure provisions of SFAS No. 123, “Accounting for Stock-Based Compensation,” 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):

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	Year Ended January 3, 2004	Year Ended December 28, 2002	Year Ended December 29, 2001
Net income (loss), as reported	\$ 371	\$ 150	\$(1,273)
Add: Total stock based compensation expense determined under fair value based method for all awards, net of tax	(534)	(438)	(727)
Pro forma net loss	<u>\$ (163)</u>	<u>\$ (288)</u>	<u>\$(2,000)</u>
Basic net income (loss) per share:			
As reported	<u>\$ 0.05</u>	<u>\$ 0.02</u>	<u>\$ (0.19)</u>
Pro forma	<u>\$(0.02)</u>	<u>\$(0.04)</u>	<u>\$ (0.30)</u>
Diluted net income (loss) per share:			
As reported	<u>\$ 0.05</u>	<u>\$ 0.02</u>	<u>\$ (0.19)</u>
Pro forma	<u>\$(0.02)</u>	<u>\$(0.04)</u>	<u>\$ (0.30)</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:

	2003		2002		2001	
	Group A	Group B	Group A	Group B	Group A	Group B
Risk-free Interest Rates	3.30%	3.30%	4.38%	4.38%	4.45%	4.40%
Expected Life from Date of Vesting	4 yrs.	2 yrs.	4 yrs.	2 yrs.	3 yrs.	2 yrs.
Volatility	0.88	0.88	0.84	0.84	0.90	0.90
Dividend Yield	—	—	—	—	—	—

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

The weighted average grant-date fair value per share of those options granted in 2003, 2002 and 2001 was \$2.96, \$2.48 and \$2.82, 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 2003, 2002 and 2001.

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 2001, 2000 and 1999:

	2003	2002	2001
Risk-free Interest Rates	1.45%	2.01%	4.63%
Expected Life	0.5 year	0.5 year	0.5 year
Volatility	0.86	0.85	0.90
Dividend Yield	—	—	—

The weighted average grant-date fair value per share of those purchase rights granted in 2003, 2002 and 2001 was \$1.01, \$1.31 and \$2.11, 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 3, 2004, December 28, 2002 and December 29, 2001 no customer accounted for greater than 10% of revenue. As of December 28, 2002 one customer accounted for 11% of accounts receivable. As of 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.

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



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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.

Reclassification

Certain prior year amounts have been reclassified to conform to the current year's presentation. These reclassifications had no impact on prior year stockholders' equity or results of operations.

Fiscal Year

Our fiscal year covers a 52 or 53 week period and ends on the Saturday nearest December 31. Fiscal year 2001 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.

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 3, 2004, 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>	
As of December 28, 2002, available-for-sale securities consisted of the following:				
Corporate notes	\$1,430	\$ 2	\$1,432	4/03 - 12/03
Foreign debt securities	523	1	524	3/03
Government agencies	400	—	400	1/03
Total	<u>\$2,353</u>	<u>\$ 3</u>	<u>\$2,356</u>	

There were no realized capital gains or losses recognized in 2003, 2002 and 2001.

	January 3, 2004	December 28, 2002
	(in thousands)	
Inventories:		
Raw materials and work in process	\$ 4,426	\$ 6,511
Finished goods	4,295	4,214
Total inventories	<u>\$ 8,721</u>	<u>\$10,725</u>
Property and Equipment:		
Equipment	\$ 3,887	\$ 3,306
Leasehold improvements	1,894	1,872
Less: accumulated depreciation and amortization	(4,931)	(4,228)
Property and equipment, net	<u>\$ 850</u>	<u>\$ 950</u>
Accrued Expenses:		
Accrued payroll, vacation and related expenses	\$ 1,009	\$ 824
Accrued warranty	801	796
Income taxes payable	733	425
Sales and use tax payable	122	325
Other accrued expenses	715	654
Total accrued expenses	<u>\$ 3,380</u>	<u>\$ 3,024</u>

4. Bank Borrowings

We have a revolving line of credit agreement with a bank expiring on October 5, 2004, which provides for borrowings of up to \$4.0 million at the bank's prime rate (4.00% at January 3, 2004). 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 3, 2004.

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 \$606,000, \$642,000 and \$498,000 for the years ended January 3, 2004, December 28, 2002 and December 29, 2001 respectively. Rental income related to a facility sublease was \$11,000 for the year ended December 29, 2001.

Future minimum lease payments under current operating leases at January 3, 2004 are summarized as follows (*in thousands*):

<u>Fiscal Year</u>	<u>Operating Lease Payments</u>
2004	\$ 379
2005	390
2006	402
2007	416
2008	429
2009	72
	<u>\$2,088</u>

License Agreements

The Company is obligated to pay royalties equivalent to 5% and 7.5% of sales on certain products under certain license agreements. Royalty expense was \$93,000, \$105,000 and \$85,000 for the years ended January 3, 2004, December 28, 2002 and December 29, 2001, 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 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 3, 2004, 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 and 2003, no shares of Common Stock were repurchased. In 2001, we repurchased 27,000 shares of Common Stock for \$115,000. As of January 3, 2004 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 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.

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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 3, 2004 was 82,422. 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 twelve-month period. The price of shares purchased under the Purchase Plan is 85% of the lower of the fair market value of the Common Stock at the beginning of the offering period or the end of the offering period. The Purchase Plan will terminate in 2005, unless terminated sooner by the Board of Directors.

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

	Outstanding Options			
	Shares Available for Grant	Number of Shares	Aggregate Price	Weighted Average Exercise Price
Balances, December 30, 2000	163,812	1,490,313	\$8,292	\$5.56
Additional shares reserved	290,000	—	—	—
Options granted	(368,050)	368,050	1,512	4.11
Options exercised	—	(74,942)	(100)	1.61
Options cancelled	(29,068)	—	—	—
Options terminated	126,604	(126,604)	(873)	7.07
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	148,424	(148,424)	(924)	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	39,114	(39,114)	(189)	4.83
Balances, January 3, 2004	313,212	2,004,283	\$9,835	\$4.91

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The following table summarizes information with respect to stock options outstanding at January 3, 2004:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$1.00 - \$1.00	76,000	1.09	\$ 1.00	76,000	\$ 1.00
\$2.00 - \$3.50	391,308	8.61	3.26	85,389	2.98
\$3.52 - \$3.71	226,425	8.02	3.66	99,849	3.71
\$3.75 - \$3.98	33,500	8.49	3.84	3,964	3.88
\$4.00 - \$4.00	405,880	3.76	4.00	405,880	4.00
\$4.01 - \$4.88	205,891	6.59	4.40	156,388	4.39
\$5.00 - \$5.50	205,875	7.34	5.28	102,897	5.27
\$5.66 - \$8.88	259,500	4.32	7.53	248,430	7.57
\$9.00 - \$12.75	192,404	6.30	9.63	168,640	9.50
\$14.88 - \$14.88	7,500	2.49	14.88	7,500	14.88
\$1.00 - \$14.88	<u>2,004,283</u>	6.14	\$ 4.91	<u>1,354,937</u>	5.29

At December 28, 2002 and December 29, 2001 options to purchase 1,184,805 and 972,249 shares of common stock were exercisable at a weighted average exercise price of \$ 5.22 and \$5.08, respectively.

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 \$89,000 in 2003 and \$98,000 in 2002. No contributions were made in fiscal 2000.

8. Income Taxes

The provision for income taxes includes:

	Year Ended January 3, 2004	Year Ended December 28, 2002	Year Ended December 29, 2001
	(In thousands)		
Current:			
Federal	\$ 19	\$ 121	\$(750)
State	9	5	—
	<u>28</u>	<u>126</u>	<u>(750)</u>
Deferred:			
Federal	(148)	(231)	(184)
State	(87)	(104)	(28)
	<u>(235)</u>	<u>(335)</u>	<u>(212)</u>
Income tax benefit	<u><u>\$(207)</u></u>	<u><u>\$(209)</u></u>	<u><u>\$(962)</u></u>

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

	Year Ended January 3, 2004	Year Ended December 28, 2002	Year Ended December 29, 2001
Income tax provision (benefit) at statutory rate	34%	(34%)	(34%)
State income taxes, net of federal benefit	6%	(6%)	(5%)
Tax exempt interest	0%	0%	(3%)
Nondeductible permanent differences	19%	56%	4%
Research and development credits	(164%)	(377%)	(28%)
Other	(22%)	1%	4%
Effective tax rate	<u><u>(127%)</u></u>	<u><u>(360%)</u></u>	<u><u>(62%)</u></u>

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

	January 3, 2004	December 28, 2002
Fixed assets	\$ 610	\$ 547
Accrued liabilities	492	414
Allowance for excess and obsolete inventories	413	366
Research credit	852	603
State tax	1	1
Allowance for doubtful accounts	47	104
Other	79	224
Net deferred tax asset	<u>\$2,494</u>	<u>\$2,259</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 3, 2004, December 28, 2002 and December 29, 2001, no customer individually accounted for more than 10% of our revenue.

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

	January 3, 2004	December 28, 2002	December 29, 2001
United States	\$20,072	\$19,564	\$16,004
Europe	5,297	5,429	5,530
Rest of Americas	1,000	833	809
Asia/Pacific Rim	5,330	4,808	4,932
	<u>\$31,699</u>	<u>\$30,634</u>	<u>\$27,275</u>

Revenues are attributed to countries based on location of customers.

In the years ended January 3, 2004, December 28, 2002 and December 29, 2001, no country individually accounted for more than 10% of our sales, except for the United States, which accounted for 63.3% of sales in 2003, 63.9% in 2002 and 58.7% in 2001.

Information on reportable segments for the three years ended January 3, 2004, December 28, 2002, and December 29, 2001 is as follows:

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	Year Ended January 3, 2004			Year Ended December 28, 2002			Year Ended December 29, 2001		
	Ophthalmology Medical Devices	Dermatology Medical Devices	Total	Ophthalmology Medical Devices	Dermatology Medical Devices	Total	Ophthalmology Medical Devices	Dermatology Medical Devices	Total
Sales	\$26,160	\$5,539	\$31,699	\$24,169	\$6,465	\$30,634	\$20,922	\$6,353	\$27,275
Direct cost of goods sold	9,217	2,782	11,999	7,917	2,844	10,761	6,772	2,595	9,367
Direct gross margin	16,943	2,757	19,700	16,252	3,621	19,873	14,150	3,758	17,908
Total unallocated indirect costs	—	—	19,748	—	—	20,054	—	—	19,897
Income (loss) from operations			\$ (48)			\$ (181)			\$ (1,989)

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

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

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

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

	Year Ended January 3, 2004	Year Ended December 28, 2002	Year Ended December 29, 2001
Income (loss) from continuing operations	\$ 371	\$ 150	\$ (601)
Income (loss) from discontinued operations	—	—	(672)
Net income (loss)	\$ 371	\$ 150	\$ (1,273)
Denominator — Net income (loss) per common share			
Weighted average common stock outstanding	6,933	6,870	6,757
Effect of dilutive securities			
Weighted average common stock options	139	58	—
Total weighted average stock and options outstanding	7,072	6,928	6,757
Basic income (loss) per common share continuing operations	\$ 0.05	\$ 0.02	\$ (0.09)
Basic income (loss) per common share discontinued operations	—	—	(0.10)
Net income (loss) per common share	\$ 0.05	\$ 0.02	\$ (0.19)
Diluted income (loss) per common share continuing operations	\$ 0.05	\$ 0.02	\$ (0.09)
Diluted income (loss) per common share discontinued operations	—	—	(0.10)
Diluted net income (loss) per common share	\$ 0.05	\$ 0.02	\$ (0.19)

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In 2003 and 2002, there were 791,406 and 1,296,391 outstanding options to purchase shares, respectively, at a weighted average exercise price 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. In 2001, there were 1,656,817 options outstanding at a weighted average exercise price of \$5.34 per share that were not included in the computation of dilutive net loss per common share because their effect was anti-dilutive due to the Company's net loss. These options could dilute earnings per share in future periods.

11. Discontinued Operations

In April 2001, we discontinued our Laser Research segment. In the first quarter of 2001, we recorded a loss of \$0.9 million (net of a \$0.5 million tax benefit). In the fourth quarter of 2001, we adjusted the loss on discontinued operations to \$0.7 million (net of a \$0.4 million income tax benefit). There were no revenues, costs or operating expenses for the Laser Research segment in 2003, 2002 or 2001. Sales, general and administrative costs and indirect costs of manufacturing historically were not allocated to the Laser Research segment.

The Laser Research segment conducted research and development under research grants from the U.S. Federal Government and others. We discontinued our Laser Research activities to better focus available resources on our medical applications and products. The assets of the segment, primarily inventory, were fully reserved and the liabilities were fully paid. The components of the recorded loss were inventory costs of \$0.7 million, the loss on operations for the first quarter of 2001 of \$0.3 million, estimated sales return costs of \$0.2 million, estimated costs for the phase-out period of \$0.1 million and purchase order commitments of \$0.1 million offset by a tax benefit of \$0.5 million. In the fourth quarter of 2001, the accrued loss for the discontinuation of the segment was adjusted to reflect fewer than anticipated product returns.

12. Selected Quarterly Financial Data, (Unaudited)

	Quarter			
	First	Second	Third	Fourth
	(In thousands, except per share amounts)			
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
Year Ended December 28, 2002				
Sales	\$6,963	\$7,433	\$6,717	\$9,521
Gross profit	\$3,085	\$3,121	\$3,012	\$4,370
Net income (loss)	\$ (207)	\$ (447)	\$ 206	\$ 598
Net income (loss) per common share	\$ (0.03)	\$ (0.07)	\$ 0.03	\$ 0.09
Diluted net income (loss) per common share	\$ (0.03)	\$ (0.07)	\$ 0.03	\$ 0.09

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

Evaluation of 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.

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 2004 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 2, 2004.

Item 10. Directors and Executive Officers of the Registrant

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

Item 11. Executive Compensation

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

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

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

Item 13. Certain Relationships and Related Transactions

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

Item 14. Principal Accountant Fees and Services.

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

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

	Page in Form 10-K Report
(a) The following documents are filed in Part II of this Annual Report on Form 10-K:	
1. Financial Statements	
Report of Independent Auditors	42
Consolidated Balance Sheets as of January 3, 2004 and December 28, 2002	43
Consolidated Statements of Operations for the years ended January 3, 2004, December 28, 2002 and December 29, 2001	44
Consolidated Statements of Stockholders' Equity for the years ended January 3, 2004, December 28, 2002 and December 29, 2001	45
Consolidated Statements of Cash Flows for the years ended January 3, 2004, December 28, 2002 and December 29, 2001	46
Consolidated Statements of Comprehensive Income (Loss) for the years ended January 3, 2004, December 28, 2002 and December 29, 2001	47
Notes to Consolidated Financial Statements	48
2. Financial Statement Schedule	
The following financial statement schedule of IRIDEX Corporation for the years ended January 3, 2004, December 28, 2002 and December 29, 2001 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	67

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

Exhibits	Exhibit Title
3.1(1)	Amended and Restated Certificate of Incorporation of Registrant
3.2(2)	Amended and Restated Bylaws of Registrant.
10.1(1)	Form of Indemnification Agreement with directors and officers.
10.2(1)	1995 Employee Stock Purchase Plan, as amended and form of agreement thereunder.
10.3(1)	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
21.1(1)	Subsidiaries of Registrant.
23.1	Consent of Independent Accountants
24.1	Power of Attorney (See page 68).
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

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- (1) Incorporated by reference to the Exhibits filed with the Registration Statement on Form SB-2 (No. 333-00320-LA) which was declared effective on February 15, 1996.
 - (2) Incorporated by reference to the Exhibits in Registrant's Report on Form 10-Q for the quarter ended October 3, 1998.
 - (3) Incorporated by reference to the Exhibits in Registrant's Proxy Statement for the Company's 1998 Annual Meeting of Stockholders which was filed April 30, 1998.
 - (4) Incorporated by reference to the Exhibits in Registrant's Report on Form 10-Q for the quarter ended September 27, 2003.

(b) Reports on Form 8-K

The Company filed a report on Form 8-K on February 4, 2004 relating to a press release regarding the Company's financial results for the fiscal quarter ended January 3, 2004.

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 29, 2001:				
Allowance for doubtful accounts receivable	\$ 481	\$(163)	\$ —	\$ 318
Provision for inventory	\$ 659	\$ 322	\$ —	\$ 981
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

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 2nd day of April, 2004.

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 2, 2004
<u>/s/ Larry Tannenbaum</u> (Larry Tannenbaum)	<i>Chief Financial Officer and Vice President, Administration (Principal Financial and Accounting Officer)</i>	April 2, 2004
<u>/s/ James L. Donovan</u> (James L. Donovan)	<i>Vice President, Corporate Business Development and Director</i>	April 2, 2004
<u>/s/ Robert K. Anderson</u> (Robert K. Anderson)	<i>Director</i>	April 2, 2004
<u>/s/ Donald L. Hammond</u> (Donald L. Hammond)	<i>Director</i>	April 2, 2004
<u>/s/ Joshua Makower</u> (Joshua Makower)	<i>Director</i>	April 2, 2004
<u>/s/ John M. Nehra</u> (John M. Nehra)	<i>Chairman of the Board</i>	April 2, 2004

Exhibit Index

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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
<hr/>	
(1)	Incorporated by reference to the Exhibits filed with the Registration Statement on Form SB-2 (No. 333-00320-LA) which was declared effective on February 15, 1996.
(2)	Incorporated by reference to the Exhibits in Registrant's Report on Form 10-Q for the quarter ended October 3, 1998.
(3)	Incorporated by reference to the Exhibits in Registrant's Proxy Statement for the Company's 1998 Annual Meeting of Stockholders which was filed April 30, 1998.
(4)	Incorporated by reference to the Exhibits in Registrant's Report on Form 10-Q for the quarter ended September 27, 2003

CONSENT OF INDEPENDENT ACCOUNTANTS

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-32161, No. 333-57573, No. 333-860191, No. 333-45736, No. 333-67480, No. 333-97541 and No. 333-10770) of IRIDEX Corporation of our report dated April 2, 2004 relating to the consolidated financial statements and financial statement schedule, which appear in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

San Jose, California
April 2, 2004

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 annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statement were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual 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 annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)), for the registrant and have:
 - a) Designed such disclosure controls and procedures or caused such disclosure controls and procedures to be designed under our supervision to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
 - b) Evaluated the effectiveness of the registrant's disclosure control and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c) Disclosed in this report any changes in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of the annual report) that has materially affected, or is reasonably likely to materially affect the registrant's internal control over financial reporting; and
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of 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 2, 2004

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 annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statement made, in light of the circumstances under which such statement were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual 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 annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) Designed such disclosure controls and procedures or caused such disclosure controls and procedures to be designed under our supervision to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
 - b) Evaluated the effectiveness of the registrant's disclosure 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 change 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 an 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 officers and I have disclosed, based on our most recent evaluation, 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 in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; 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 2, 2004

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

In connection with the Annual Report of IRIDEX Corporation (the "Company") on Form 10-K for the year ending January 3, 2004, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Theodore A. Boutacoff, Chief Executive Officer, and Larry Tannenbaum, Chief Financial Officer, of the Company, each certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission upon request.

Date: April 2, 2004

By: /s/ THEODORE A. BOUTACOFF

Name: Theodore A. Boutacoff
Title: President and Chief Executive Officer
(Principal Executive Officer)

Date: April 2, 2004

By: /s/ LARRY TANNENBAUM

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