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 UNITED STATES  
 SECURITIES AND EXCHANGE COMMISSION  
 WASHINGTON D.C. 20549  
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## FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
 SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED DECEMBER 30, 2000

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  
 (ADDRESS OF PRINCIPAL EXECUTIVE OFFICES)

94043-1824  
 (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, \$0.01 PAR VALUE

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 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.

The aggregate market value of the voting stock held by non-affiliates of the Registrant as of March 20, 2001, was approximately \$13,617,831 based on the closing price reported for such date on the NASDAQ National Market System. 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 20, 2001, Registrant had 6,706,135 shares of Common Stock outstanding.

## DOCUMENTS INCORPORATED BY REFERENCE

Certain parts of the Proxy Statement for the Registrant's 2001 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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## TABLE OF CONTENTS

	PAGE
	----
PART I	
Item 1. Business.....	1
Item 2. Properties.....	15
Item 3. Legal Proceedings.....	15
Item 4. Submission of Matters to a Vote of Security Holders.....	15
PART II	
Item 5. Market for Registrants' Common Equity and Related Stockholder Matters.....	16
Item 6. Selected Financial Data.....	17
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.....	18
Item 7A. Quantitative and Qualitative Disclosure about Market Risk...	27
Item 8. Financial Statements and Supplementary Data.....	27
Item 9. Disagreements on Accounting and Financial Disclosure.....	46
PART III	
Item 10. Directors and Executive Officers of the Registrant.....	46
Item 11. Executive Compensation.....	46
Item 12. Security Ownership of Certain Beneficial Owners and Management.....	46
Item 13. Certain Relationships and Related Transactions.....	46
PART IV	
Item 14. Exhibits, Financial Statement Schedules and Reports on Form 8-K.....	47
Signatures.....	49

## PART I

This Annual Report on Form 10-K (The "Form 10-K") contains certain forward-looking statements within the meaning of section 21E of the Securities Exchange Act of 1934, as amended, (the "Exchange Act"), such as statements relating to levels of future investment in research and development; the development of new, more cost-effective technologies, therapeutic and adjunctive diagnostic systems, strategic alliances, new delivery devices and the OcuLight 664; the timing of the release of our Apex 800 product; the effect of consumer education and managed care on the demand for our products; the effect of HCFA's reimbursement policies on future sales and the likelihood that such policies will change expectations for future growth in unit sales; expectations for future sales growth, generally, and the potential for production cost decreases and higher gross margin. 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 actual results, performance or achievements of the Company to differ materially from those expressed or implied by such forward-looking statements. Such factors include, among others, 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. 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. The Company undertakes no obligation to update these forward-looking statements. The reader is strongly urged to read the information set forth 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" for a more detailed description of these significant risks and uncertainties.

## ITEM 1. BUSINESS

## GENERAL

IRIDEX Corporation ("IRIDEX") is the leading worldwide provider of semiconductor-based laser systems used to treat eye diseases in ophthalmology and skin lesions in dermatology. Our products are sold in the United States predominantly through a direct sales force and internationally through 54 independent distributors into 74 countries.

Our ophthalmology products treat eye diseases, including the three leading causes of irreversible blindness. The current family of ophthalmology laser systems includes the IRIS Medical OcuLight SL, OcuLight SLx, OcuLight GL and OcuLight GLx Laser Photocoagulation systems (each an "OcuLight System"). Our dermatology products, including the IRIDERM DioLite 532 Laser System, treat skin diseases, primarily vascular and pigmented lesions. Each ophthalmic and dermatologic system consists of a small, portable laser console and interchangeable delivery devices, primarily for hospital and office-based use by ophthalmologists and dermatologists. We believe that our semiconductor-based systems are more portable, economical, reliable and flexible than competing systems which use traditional vacuum tube-based technology. Since our first shipment in 1990, more than 4,200 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. 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, and IRIDEX Foreign Sales Corporation, a Barbados corporation, and our dermatology division, IRIDERM.

## THE IRIDEX STRATEGY

We are one of the worldwide leaders in developing, manufacturing, marketing and selling innovative and cost-effective medical laser systems. The key elements of our strategy are:

**Broaden Product Lines by Leveraging Existing Technology.** In 1996, we introduced a new visible laser system, the OcuLight GL, for ophthalmology. In 1997, we introduced the DioLite 532, based on the same visible 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. The characteristics of these new products are similar to those which have made our previous products successful, such as low cost ownership, reliability and portability.

**Develop and Validate New Applications.** We seek to develop and validate applications that are less costly, reduce complications and achieve better clinical results than existing treatments. Our products are currently being used in multiple studies in the United States and internationally to demonstrate the clinical benefits of our technology in treatment. Our OcuLight SLx laser is being used in several studies to treat the various stages of age-related macular degeneration (AMD). Additionally, two international studies are evaluating the use of our G-Probe as a primary treatment for glaucoma. We announced in October 1999 that a study on occult wet AMD produced results demonstrating that Transpupillary Thermotherapy (TTT) was effective in improving or stabilizing vision in 75% of patients with a procedure using our OcuLight infrared laser photocoagulator. In March 2000 enrollment commenced in a Company supported twenty center clinical trial which could validate TTT as an effective therapy for the majority of patients with wet AMD, the leading cause of blindness in the western world. New applications increase laser usage and may ultimately increase the size of the market for laser photocoagulators.

**Continue to Enhance Products.** One of our core strengths has been our regular introduction of new delivery devices and product upgrades to enhance the benefits of our laser systems. In October 1999, we introduced the next generation of OcuLight SLx, which offers added features, such as LongPulse(TM) and MicroPulse(TM) operating modes. These features enable the OcuLight SLx to perform the latest in clinical infrared applications. In September 1998, we introduced our next generation of portable Slit Lamp Adapters, which offer superior viewing ability. This superior viewing ability results from new UltraView optics combined with precision laser beam steering using a new self-centering micromanipulator. We intend to continue our investment in research and development to improve the performance of our systems. We also intend to develop additional technologies which can more cost effectively address the needs of the ophthalmic and dermatologic markets. To enhance our research and development efforts, we collaborate with an extensive network of academic leaders who provide input and advice, as well as assist in validating the efficacy of new products and applications.

**Expand Medical Practice Versatility.** We provide products that allow ophthalmologists to expand their practice by increasing the offering of delivery services available to them and adding to the clinical procedures that can be performed in the ophthalmologist's office. In September 1998, we obtained clearance from the FDA for a Dermatology Kit that allows our OcuLight GL laser photocoagulator, which is currently used by ophthalmologists to treat a variety of eye diseases, to also treat vascular and pigmented skin lesions.

**Provide Total Disease Management.** We intend to pursue both therapeutic and adjunctive diagnostic systems. An adjunctive diagnostic system is used either to screen and identify more patients who require therapy or objectively assess the adequacy of therapy. We believe that a significant opportunity exists to provide diagnostic equipment to the ophthalmic and optometric communities. We intend to pursue our entrance into this diagnostic market through both internal development and selected acquisitions. By pursuing therapeutic and diagnostic systems, we intend to provide total disease management.

**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. We have been working with Miravant Medical Technologies, formerly known as PDT, Inc. ("Miravant"), a company engaged in the development of

photodynamic drugs and applications, to provide lasers to activate certain photodynamic drugs developed by Miravant.

## 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 system and add additional delivery devices as their needs expand or as we develop new applications. This systems approach also brings economies-of-scale to our product development and manufacturing efforts since each application does not require the design and manufacture of complete stand-alone products. Our primary non-disposable products range in price from \$2,000 to \$50,000.

**Consoles:** Our laser consoles incorporate the economic and technical benefits of semiconductor laser technology, which is the basis of our semiconductor-based laser systems.

**Infrared Photocoagulator Consoles.** These OcuLight photocoagulator consoles are available in two infrared 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.

**Veterinary Infrared Console.** The DioVet laser system is used by veterinary ophthalmologists worldwide to treat glaucoma, retinal disorders, and tumors in dogs, cats, horses and other animals. The laser's 810 nm wavelength enables transscleral glaucoma and retinal procedures that are less traumatic and painful than cryotherapy while providing greater accuracy to the treatment area. The small size of the DioVet allows easy transport to multiple clinics or remote locations.

**Visible Photocoagulator Consoles.** Our semiconductor-based photocoagulator, the OcuLight GL delivers visible laser light. The OcuLight GLx, a new version of the OcuLight GL, has increased power and delivery device capability. Our dermatology product, the DioLite 532, is also based on visible semiconductor-based technology. These 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.

**Peripheral Delivery Devices:** Our versatile family of consoles and delivery devices has been designed to allow the addition of new capabilities with a minimal incremental investment. A user adds capabilities by simply purchasing a new interchangeable delivery device. 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 worn on the physician's head and is used to treat peripheral retinal disorders, particularly in infants or adults requiring treatment in the supine position. This product can be used both for diagnosis and treatment at the point-of-care.

**Slit Lamp Adapter.** These adapters allow the physician to utilize a standard slit lamp for both diagnosis and treatment. A slit lamp adapter can be installed by the doctor in several minutes, converting over 50 variations of a standard diagnostic slit lamp into a therapeutic photocoagulator delivery system. Slit lamp adapters are used for treatment of both retinal and glaucoma diseases.

**Operating Microscope Adapter.** These adapters allow the physician to utilize a standard operating microscope for both diagnosis and laser treatment. These devices are similar to slit lamp adapters, except 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 performed in the hospital operating room or surgery center. These sterile disposable probes are available in tapered, angled, fluted, active aspiration and illuminating styles.

G-Probe. The G-Probe is used 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 about 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 to treat retinal tears and breaks transsclerally, noninvasively through the sclera as an alternative method of attaching the retina. Advantages include 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 to treat vascular and pigmented lesions. These devices are available in 200, 500, 700, 1000 and 1400 micron sizes.

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 lesions including port wine stains, matted telangiectasia, and cafe au lait stains.

We have also developed a new laser system with Miravant. This system emits a laser beam to activate a photodynamic drug being developed by Miravant in order to achieve a therapeutic result in the treatment of AMD. Clinical studies are being evaluated to test the efficacy of this procedure. Miravant has entered into a co-development agreement with Pharmacia & Upjohn to more rapidly develop the photodynamic drug and validate its use in clinical studies. We expect that, if successful, the development of this product and the receipt of the appropriate regulatory approval thereof will occur within two years. See Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations -- Factors That May Affect Our Future Results -- We Depend on Third Party Coverage and Reimbursement Policies -- We Depend on Development of New Products and New Applications and -- We Depend on Collaborative Relationships."

In March 1999, we announced a new laser system, the APEX(TM) 800 for hair removal. We expect units to be available for shipment during the first half of 2001.

The following chart lists the eye diseases that can be treated using our photocoagulator systems, including the preferred delivery devices. The selection of delivery device is often determined by the severity and location of the disease. The chart also lists the skin diseases or conditions that can be treated with the DioLite 532.

CONDITION -----	PROCEDURE -----	CONSOLE -----	DELIVERY DEVICES -----
Ophthalmology Treatments:			
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
Proliferative	Focal Retinal Photocoagulation	Visible	Slit Lamp Adapter
	Pan-Retinal Photocoagulation	Infrared & Visible	Slit Lamp Adapter, Operating Microscope Adapter, Laser Indirect Ophthalmoscope, EndoProbe
Glaucoma			
Primary Open-Angle	Trabeculoplasty	Infrared & Visible	Slit Lamp Adapter
Angle-closure	Iridotomy(1)	Infrared & Visible	Slit Lamp Adapter
Uncontrolled	Transscleral Cyclophotocoagulation	Infrared	G-Probe
Retinal Detachment	Retinopexy Retinal Photocoagulation	Infrared & Visible	Slit Lamp Adapter, Laser Indirect Ophthalmoscope, Operating Microscope Adapter, EndoProbe
	Transscleral Retinal Photocoagulation	Infrared	DioPexy Probe
Retinopathy of Prematurity	Retinal Photocoagulation	Infrared	Laser Indirect Ophthalmoscope
Ocular Tumors	Retinal Photocoagulation	Infrared	Slit Lamp Adapter, Operating Microscope Adapter, Laser Indirect Ophthalmoscope
Dermatology Treatments:			
Vascular Lesions	Selective Photothermolysis	Visible	DioLite Handpiece
Pigmented Lesions	Selective Photothermolysis	Visible	DioLite Handpiece

(1) This indication is currently not cleared by the U.S. FDA.

#### RESEARCH AND DEVELOPMENT

Our research and development activities are performed internally by our research and development staff comprised of 26 individuals and are supplemented by consultants with specialized expertise. Research and development efforts are directed toward both development of new products and development of new applications using existing products. Our expenditures for research and development totaled approximately \$5,265,000, \$3,925,000 and \$3,099,000 in 2000, 1999 and 1998, respectively. We have close working relationships with ophthalmic researchers, clinicians and dermatologists 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 supporting pre-clinical and clinical studies to develop new photocoagulation treatments and applications. 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 include:

#### Ophthalmic Applications:

Age-Related Macular Degeneration (AMD) -- Dry Form. About 90% of AMD is the dry form. We are pursuing two approaches to treat dry AMD: Therapeutic Treatment and Prophylactic Treatment. The Therapeutic Treatment approach uses the OcuLight infrared laser to restore vision by causing resorption of dry AMD deposits which have accumulated in the macula and have impacted vision. For Prophylactic Treatment, we are supporting a randomized multi-center clinical trial which is testing a prophylactic treatment of age-related macular degeneration (PTAMD trial). This trial treats patients with dry AMD using our OcuLight infrared laser systems with the objective of reducing the rate of progression of the disease from the dry form of AMD to the wet form of AMD. We are also evaluating whether patient vision improves as a result of this application.

Age-related Macular Degeneration (AMD) -- Wet Form. The wet form of AMD constitutes about 10% of all AMD but accounts for about 80% of all severe vision loss associated with AMD. We are pursuing three approaches to treat wet AMD to treat the disease at different stages: Photodynamic Therapy (PDT), Transpupillary Thermotherapy (TTT) and Feeder Vessel Treatment. All of these approaches close new vessels in the macula caused by wet AMD with less damage than conventional laser treatments. In the PDT approach, an infused photodynamic drug is stimulated by one of our lasers to close the new vessels. We are collaborating with Miravant and Pharmacia in commercializing this PDT approach to treat "classic" wet AMD. The Phase III clinical trial was fully enrolled in December 1999. In January of 2001, Miravant and Pharmacia announced that two year results would be used for an FDA filing. In the TTT approach a certain form of wet AMD called "occult" is treated with the infrared laser alone. Favorable results of a pilot study were published in October 1999 and a multi-center randomized trial called the TTT4CNV Trial, which we are supporting, is currently enrolling patients. For Feeder Vessel Treatment, two centers, one in Europe and one in the U.S., are using our infrared laser in clinical studies to treat both "classic" and "occult" wet AMD. Favorable results have been reported by both centers.

Glaucoma. Preliminary studies are underway to evaluate the use of the G-Probe as a first-line treatment modality for various glaucomas.

Diabetic Retinopathy. Studies are underway to investigate the treatment of diabetic retinopathy using MicroPulse (minimal impact sub-visible threshold) infrared photocoagulation with the objective of causing regression of the disease with less loss of vision than conventional therapy.

Ocular Tumors. Clinical studies have reported successful treatment of ocular tumors using OcuLight infrared lasers using an approach called Transpupillary Thermotherapy (TTT).

#### CUSTOMERS AND CUSTOMER SUPPORT

Our products are currently sold to ophthalmologists, including glaucoma specialists, retinal specialists, pediatric ophthalmologists, and dermatologists. 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 2000, 1999 or 1998. See "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. We currently estimate that there are approximately 20,000 ophthalmologists in the United States and 50,000 internationally who are each potential customers. We believe there are approximately 10,000 dermatologists in the U.S. Additionally, we estimate that there are approximately 4,700 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. 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, hospital and medical center is a potential customer for our products. We are seeking to broaden our customer base by developing new diagnostic products directed at addressing the needs of ophthalmologists and dermatologists.

We seek to provide superior customer support and service. An "around-the-clock" telephone service line is maintained to service 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 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

To support our sales process, we conduct marketing programs which include direct mail, trade shows, public relations, advertising in trade and academic journals and newsletters. We annually participate in approximately 87 trade shows or meetings in the United States and 65 trade shows or meetings internationally. These meetings allow us to present our products to existing and prospective buyers. While the sales cycle varies from customer to customer, it averages 12 months and typically ranges from two to 24 months. Our sales and marketing organization is based at our corporate headquarters in Mountain View, California with area sales managers located in California, Florida, Georgia, Illinois, Maryland, Massachusetts, Missouri, New Jersey, Ohio, Texas, and Virginia.

International product sales represented 35.6%, 38.4% and 36.5% of our sales in 2000, 1999 and 1998, respectively. Our products are sold internationally through our 54 independent distributors into 74 countries and in the United States predominantly through our direct sales force. International sales are administered through our corporate headquarters in Mountain View, California, along with four area sales managers. Our distribution agreements with our international distributors are generally exclusive and typically can be terminated by either party without cause on 90 days notice. See "Management's Discussion and Analysis of Financial Condition and Results of Operations -- Factors That May Affect Future Results -- We Depend on International Sales."

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 at an early stage 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 laser products as well as our prospective diagnostic products.

We work with our customers to enhance our ability to identify new applications for our products, validate new procedures using our products, respond more effectively to new procedures and expedite regulatory approvals of new products and applications. Customers include key opinion leaders who are often the heads of the departments or professors at universities. These luminaries in the field of ophthalmology and dermatology are key to the successful introduction of new technologies and their subsequent acceptance by the general market. Acceptance of our products by these early adopters is key to our strategy in the validation of our technology. In addition, we believe that widespread adoption of our laser platforms will require education about our products as compared to competing systems.

#### OPERATIONS

The manufacture of ophthalmic and dermatologic laser systems is a complex process involving precision components, intricate procedures, and environmental controls. Completed systems must pass quality control and reliability tests before shipment. We purchase substantially all of our components that are either standard or built to proprietary specifications and subassemblies from various independent suppliers and subcontractors. We assemble critical subassemblies and the final product at our Mountain View, California facility. Most of the sub-contractors are located within 10 miles of our Mountain View facility. Some of our suppliers are

relatively small private companies that may discontinue their operations at any time. There are risks associated with the use of independent suppliers and sub-contractors, including unavailability of or delays in obtaining adequate supplies of components, including optics, laser diodes and crystals, and potentially reduced control of quality, production costs and the timing of delivery. As an example, in the past, we have experienced delays in the manufacturing of our OcuLight GL due to the inability of a supplier to deliver certain laser diode components in volume and on a timely basis. We may experience difficulty identifying alternate sources of supply for certain components used in our products. In addition, the use of alternate components may require design alterations, which may delay installation and increase product cost. 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. Establishing our own capabilities to manufacture these components would require significant scale-up expenses and additions to facilities and personnel and could adversely affect our earnings.

The process of qualifying suppliers is ongoing and may be lengthy, particularly as new products are introduced. However, we have qualified two or more sources for most of the components used in our products. We continue to work with our suppliers to ensure that such difficulties do not recur. We have some long-term or volume purchase agreements with our suppliers and currently purchase components on a purchase order basis. These components may not be available in the quantities required, on reasonable terms, or at all. Our business, financial condition and results of operations would be adversely affected if we were unable to obtain components in the quantities required at a reasonable cost and on a timely basis, or if we could not expand manufacturing capacity to meet demand or if operations at our single facility were disrupted. 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."

In April 1998, we received certification for ISO 9001/EN 46001. ISO 9001/EN 46001 is a documented international quality system demonstrating compliance to the European Medical Device Directive.

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" registered, 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 registration under Annex II guidelines, the most stringent path to CE registration. With Annex II CE registration, we have demonstrated our ability to both understand and comply with all applicable European standards. This allows us to register any product upon our internal verification of compliance to all applicable European Standards. Currently, all released products are CE registered. Continued registration is based on successful review of the process by our European Registrar during its annual audit. Any loss of registration would have a material adverse effect on our business, results of operations and financial condition.

#### COMPETITION

Competition in the market for devices used for ophthalmic and dermatologic treatments 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, we compete with pharmaceuticals, solutions, other technologies and other surgical techniques. Our principal competitors in ophthalmology are Coherent, Inc., Nidek, Inc. ("Nidek"), Carl Zeiss, Inc. ("Zeiss"), Quantel, Alcon International, and HGM Medical Laser Systems, Inc. ("HGM"). Of these companies, all currently offer a competitive, semiconductor-based laser system in ophthalmology. Our principal competitors in dermatology are Laserscope and HGM. The Apex 800 laser hair removal system will compete with products from Coherent, Inc., Candela Corporation, ESC Medical Systems, Ltd. and Cynosure, Inc. Some competitors have substantially greater financial, engineering, product development, manufacturing, marketing and technical resources than we do. Such companies also have greater name recognition than us and long-standing customer relationships. In addition, other medical companies, academic and research institutions, or others, may develop new technologies or therapies, including medical devices, surgical procedures or pharmacological

treatments and obtain regulatory approval for products utilizing such techniques that are more effective in treating the conditions targeted by us, or are less expensive than our current or future products. Our technologies and products could be rendered obsolete by such developments. Any such developments could have a material adverse effect on our business, financial condition and results of operations. See Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations -- Factors That May Affect Future Results -- Our Market is Competitive."

#### PATENTS AND PROPRIETARY RIGHTS

Our success and ability to compete is dependent in part upon our proprietary information. We rely on a combination of patents, trade secrets, copyright and trademark laws, nondisclosure and other contractual agreements and technical measures to protect our intellectual property rights. We file patent applications to protect technology, inventions and improvements that are significant to the development of our business. We have been issued ten United States patents on the technologies related to our products and processes. There can be no assurance that any of our patent applications will issue as patents, that any patents now or hereafter held by us will offer any degree of protection, or that our patents or patent applications will not be challenged, invalidated or circumvented in the future. 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 January 2000, we received a new patent on technology that allows IRIDEX products to provide "power on demand," which enables the manufacture of small, portable, solid-state laser products with highly accurate control of treatment parameters.

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. 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. Because patent applications are maintained in secrecy in the United States until patents are issued and are maintained in secrecy for a period of time outside the United States, we have not conducted any searches to determine whether our technology infringes any patents or patent applications. 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. This may adversely impact our operating results.

Any claims, with or without merit, could 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. Although patent and intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. An adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses 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.

#### 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 Food and Drug Administration (the "FDA") serves as the principal federal agency 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, 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 their safety and effectiveness. 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.

Before a new device can be introduced into the market, the manufacturer must generally 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 predicate 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 from the date of submission to grant a 510(k) clearance, but it may take longer. In December 1999, the FDA granted a 510(k) clearance for the Company's new APEX 800 hair removal laser.

A "not substantially equivalent" determination, or a request for additional information, could delay the market introduction of new products that fall into this category and could have a materially adverse effect on our business, financial condition and results of operations. For any of our products that are cleared through the 510(k) process, modifications or enhancements that could significantly affect the safety or efficacy of the device or that constitute a major change to the intended use of the device will require new 510(k) submissions.

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

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.

All of our products have obtained either an independent 510(k) clearance or are modifications of previously cleared 510(k) devices, which do not require the submission of a new 510(k) notification. However, the FDA may not agree with our determination that a 510(k) notification is not required for the modified devices and require us to submit a new 510(k) notification for the modification. If the FDA requires us to submit a new 510(k) notification for the modified devices, we may be prohibited from marketing the modified device until the 510(k) notification is cleared by the FDA.

We have also established a strategic alliance with Miravant to manufacture a device designed to photoactivate an ophthalmic drug currently under development by Miravant. Miravant is responsible for obtaining the required regulatory approvals. Under the FDA's combination products policy, the ophthalmic drug and photoactivating device may be considered a drug-device combination product and, therefore, be required to undergo the new drug approval process. The steps required before a new drug can be commercially distributed in the United States include (1) conducting appropriate pre-clinical laboratory and animal tests, (2) submitting to the FDA an application for an investigational new drug ("IND"), which must become effective before clinical trials may commence, (3) conducting well-controlled human clinical trials that establish the safety and effectiveness of the drug, (4) filing a new drug application ("NDA") with the FDA, and (5) obtaining FDA approval of the NDA prior to any commercial distribution of the drug. The new drug approval process is expensive, lengthy and uncertain, and many new drug products have never been approved for marketing. An approved NDA may be required for the ophthalmic drug and photoactivating device as a combination product. If required, we may not be able to obtain such approval. In addition, the FDA may require separate premarket clearance for the photoactivating device through either a 510(k) notification or a PMA. If required, we may not be able to obtain such premarket clearance or approval.

Any products manufactured or distributed by us pursuant to FDA clearances or approvals are subject to pervasive and continuing regulation by the FDA, including recordkeeping requirements and reporting of adverse experiences with the use of the device. Device manufacturers are required to register their establishments and list their devices with the FDA and certain state agencies, and are subject to periodic inspections by the FDA and certain state agencies. The FDA Act requires devices to be manufactured to comply with applicable QSR regulations which impose certain procedural and documentation requirements upon us with respect to manufacturing, design, development and quality assurance activities.

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.

The introduction of our products in foreign markets will also subject us to foreign regulatory clearances which may impose additional substantial 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

Our products are typically purchased by doctors, clinics, hospitals and other users, which bill various third-party payors, such as governmental programs and private insurance plans, for the health care services provided to their patients. Third-party payors carefully review and are increasingly challenging the prices charged for medical products and services. Reimbursement rates paid by third party payors may vary depending on the procedure performed, the third-party payor, the insurance plan and other factors. Medicare reimburses hospitals on a prospectively-determined fixed amount for the costs associated with an in-patient hospitalization based on the patient's discharge diagnosis. Medicare 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. Third-party

payors are increasingly scrutinizing whether to cover 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 payors. While we believe that the laser procedures using our products have generally been reimbursed, payors 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 Health Care Financing Administration (HCFA) advised that claims for reimbursement for certain AMD procedures that use our OcuLight SLx laser system would not be reimbursed by Medicare. In September 2000, HCFA changed its position and advised that claims for reimbursement for these AMD procedures can be submitted for reimbursement with coverage and payment to be determined by the local Medicare carriers at their discretion. As a result, since July 2000, sales of the OcuLight SLx laser system have dropped significantly. Sales of the OcuLight SLx continue, albeit at a lower level, because the OcuLight SLx can also be used for other ophthalmic procedures with Medicare reimbursement. Furthermore, since HCFA policies apply only to third party Medicare payors, 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 Medicare carriers elect to cover and reimburse for performing such AMD procedures or until HCFA advises that claims for these procedures are Medicare covered and reimburseable. We believe that more Medicare carriers will reimburse for these procedures or HCFA will allow national standardized reimbursement for them when they are further validated by clinical studies. The Company is supporting a randomized clinical trial to further validate Transpupillary Thermal Therapy, the most significant of the subject AMD procedures. See "Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations -- Results of Operations-Sales."

We have developed a new laser system with Miravant, the Oculight 664. Miravant may not be able to obtain coverage for its use of drugs with our OcuLight Systems, or the reimbursement may not be adequate to cover the treatment procedure. Changes in government legislation or regulation or in private third-party payors' policies toward reimbursement for procedures employing our products may prohibit adequate reimbursement. Denial of coverage and reimbursement for our products could have a material adverse effect on our business, results of operations and financial condition. 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.

Most of the treatment procedures for dermatology using our DioLite 532 laser systems are billed to private-pay customers. Accordingly, reimbursement issues for our dermatology systems are insignificant.

#### 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.

## BACKLOG

We generally ship our products within a few days after acceptance of a customer's purchase order. Accordingly, we do not believe that our backlog at any particular time is indicative of future sales levels.

## EMPLOYEES

At December 30, 2000, we had a total of 121 full-time employees, including 47 in operations, 36 in sales and marketing, 26 in research and development and 12 in finance and administration. We also employ, from time to time, a number of temporary and part-time employees as well as consultants on a contract basis. At December 30, 2000, we employed 3 such persons. We intend to hire additional personnel during the next twelve months in each of these 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.

## EXECUTIVE OFFICERS OF THE COMPANY

Our executive officers and their ages as of December 30, 2000 were as follows:

NAME ----	AGE ---	POSITION -----
Theodore A. Boutacoff.....	53	President, Chief Executive Officer and Director
Robert Kamenski.....	46	Chief Financial Officer and Vice President, Administration
Eduardo Arias.....	56	Senior Vice President, Worldwide Sales
Timothy Powers.....	39	Vice President, Operations
James L. Donovan.....	63	Vice President, Corporate Business Development and Director

Mr. Boutacoff co-founded IRIDEX and since February 1989 has served as its President, Chief Executive Officer and a member of its Board of Directors. Prior to co-founding the Company, Mr. Boutacoff held various positions, including Director of New Business and Clinical Development, Director of Marketing and Director of Regulatory Affairs, with the Medical Division of Coherent, Inc., a manufacturer of laser systems for science, medicine and industry. Mr. Boutacoff holds a B.S. degree in civil engineering from Stanford University.

Mr. Kamenski joined IRIDEX in March 1997 as Vice President, Finance and Administration and was appointed Chief Financial Officer in October 1997. Prior to joining us, from July 1992 to March 1997, Mr. Kamenski held various positions, including Chief Financial Officer and Vice President of Finance and Administration, with TeleSensory Corporation. Mr. Kamenski holds a B.B.A. degree in accounting from the University of Wisconsin-Milwaukee.

Mr. Arias co-founded IRIDEX and served as Vice President, Sales & Marketing from April 1989 until September 1991 when he was promoted to the position of Senior Vice President, Worldwide Sales. Prior to co-founding the Company, Mr. Arias held various positions, including Director of Marketing and Sales, Medical Group and Director of International Operations, at Coherent, Inc.

Mr. Powers joined IRIDEX in July 1997 as Vice President, Operations. Prior to joining us, from November 1988 to July 1997, Mr. Powers held various positions, including Vice President of Operations, at Strato/Infusaid, Inc., a Pfizer subsidiary. Mr. Powers holds a Masters of Management Science degree in manufacturing engineering and a Bachelors of Science degree in industrial technology, both from the University of Lowell in Massachusetts.

Mr. Donovan co-founded IRIDEX and, since February 1989, has served as a member of our Board of Directors. From February 1989 to October 1997, Mr. Donovan served as our Chief Financial Officer, except in the period June to November 1996, and is currently serving as our Vice President, Corporate Business Development. Prior to co-founding the Company, Mr. Donovan served as General Manager of the Medical Division and Chief Financial Officer of Coherent, Inc. Mr. Donovan holds a B.S. degree in business administration from Southern Oregon State College.



## ITEM 2. PROPERTIES

Our operating facilities are located in 37,000 square feet of space in Mountain View, California. The building houses manufacturing, research and development and serves as our headquarter offices. The lease term expires in 2002 and contains renewal options.

Management believes that our facility will be 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

None.

## ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of security holders during the fourth quarter of the fiscal year covered by this report.

## PART II

## ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

## MARKET INFORMATION FOR COMMON EQUITY

Our Common Stock has been traded 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 closing prices for our Common Stock.

	HIGH -----	LOW -----
FISCAL 2001		
First Quarter (through March 20, 2001).....	\$ 6.313	\$4.125
FISCAL 2000		
First Quarter.....	\$17.000	\$8.000
Second Quarter.....	13.000	8.375
Third Quarter.....	12.000	7.625
Fourth Quarter.....	11.375	4.875
FISCAL 1999		
First Quarter.....	\$ 5.750	\$3.875
Second Quarter.....	5.125	3.625
Third Quarter.....	5.000	3.625
Fourth Quarter.....	9.500	4.188

## FISCAL 2001

On March 20, 2001, the closing price on the NASDAQ National Market for our Common Stock was \$4.375 per share. As of December 30, 2000, there were approximately 90 holders of record of our Common Stock.

## 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.

## ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data as of December 30, 2000 and January 1, 2000, and for the years ended December 30, 2000, January 1, 2000 and January 2, 1999, has been derived from, and are qualified by reference to, our audited consolidated financial statements included herein. The selected consolidated statement of income data as of December 31, 1997 and 1996 and the consolidated balance sheet data as of January 2, 1999, December 31, 1997 and 1996 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 the consolidated financial statements included in Item 8. "Financial Statements and Supplementary Data."

	2000	1999	1998	1997	1996
	-----	-----	-----	-----	-----
CONSOLIDATED STATEMENT OF INCOME DATA:					
Sales(1).....	\$33,437	\$26,852	\$23,644	\$18,098	\$12,372
Cost of sales(1).....	14,638	11,878	10,367	7,637	4,907
	-----	-----	-----	-----	-----
Gross profit.....	18,799	14,974	13,277	10,461	7,465
	-----	-----	-----	-----	-----
Operating expenses:					
Research and development.....	5,265	3,925	3,099	1,716	1,286
Selling, general and administrative.....	10,747	9,224	8,358	6,074	5,197
	-----	-----	-----	-----	-----
Total operating expenses.....	16,012	13,149	11,457	7,790	6,483
	-----	-----	-----	-----	-----
Income from operations.....	2,787	1,825	1,820	2,671	982
Other income, net.....	569	556	511	607	699
	-----	-----	-----	-----	-----
Income before provision for income taxes.....	3,356	2,381	2,331	3,278	1,681
Provision for income taxes.....	(940)	(763)	(583)	(1,180)	(676)
	-----	-----	-----	-----	-----
Net income.....	\$ 2,416	\$ 1,618	\$ 1,748	\$ 2,098	\$ 1,005
	=====	=====	=====	=====	=====
Net income per common share(2).....	\$ 0.36	\$ 0.25	\$ 0.27	\$ 0.33	\$ 0.18
	=====	=====	=====	=====	=====
Shares used in per common share calculation(2).....	6,637	6,503	6,480	6,406	5,725
	=====	=====	=====	=====	=====
Diluted net income per common share(2).....	\$ 0.33	\$ 0.24	\$ 0.26	\$ 0.31	\$ 0.16
	=====	=====	=====	=====	=====
Shares used in diluted income per common share calculation(2).....	7,285	6,849	6,765	6,755	6,410
	=====	=====	=====	=====	=====

	DECEMBER 30,	JANUARY 1,	JANUARY 2,	DECEMBER 31,	
	2000	2000	1999	1997	1996
	-----	-----	-----	-----	-----
CONSOLIDATED BALANCE SHEET DATA:					
Cash, cash equivalents and available-for-sale securities.....	\$12,994	\$13,148	\$10,876	\$13,488	\$15,114
Working capital.....	27,005	23,842	23,450	21,716	20,777
Total assets.....	35,025	32,763	28,377	26,686	23,707
Total stockholders' equity.....	30,500	27,504	25,885	23,880	21,478

(1) Sales and cost of sales figures have been revised as a result of the retroactive adoption of EITF 00-10 "Accounting for Shipping and Handling Fees and Costs."

(2) See Note 10 of Notes to Consolidated Financial Statements for an explanation of shares used in per share calculations.

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The discussion in Management's Discussion and Analysis of Financial Condition and Results of Operations contains trend analysis and other 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. Actual results could differ materially from those set forth in such forward-looking statements as a result of the factors set forth under "Factors That May Affect Future Results" and other risks detailed from time to time in our reports filed with the Securities and Exchange Commission.

### OVERVIEW

IRIDEX Corporation is the leading worldwide provider of semiconductor-based laser systems used to treat eye diseases in ophthalmology and skin lesions in dermatology. Our products are sold in the United States predominantly through a direct sales force and internationally through 54 independent distributors into 74 countries.

Our ophthalmology products treat eye diseases, including the three leading causes of irreversible blindness. The current family of ophthalmology laser systems includes the IRIS Medical OcuLight SL, OcuLight SLx, OcuLight GL and OcuLight GLx Laser Photocoagulation systems (each an "OcuLight System"). Our dermatology products treat skin diseases, primarily vascular and pigmented lesions. In June 1997, we launched the IRIDERM DioLite 532 Laser System to address the dermatology market. The DioLite 532 Laser System is sold primarily for office-based use by dermatologists. Each ophthalmic and dermatology system consists of a small, portable laser console and interchangeable delivery devices, primarily for hospital and office-based use by ophthalmologists and dermatologists. We believe that our semiconductor-based systems are more portable and economical and have a greater degree of reliability and flexibility than competing systems which use traditional vacuum tube-based technology. Since our first shipment in 1990, more than 4,200 IRIDEX medical laser systems have been sold worldwide.

Our revenues arise primarily from the sale of our IRIS Medical OcuLight Systems, IRIDERM DioLite 532 systems, delivery devices, disposables and, to a lesser extent, revenues from service and support activities, and the sale of Light Solutions products and research grants. 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. Revenue from services is recognized upon performance of the applicable services. Our sales have increased primarily due to growth in unit sales (including additional unit sales resulting from the introduction of the DioLite 532 in June 1997 and OcuLight GLx in January 1999), greater market penetration and an expanded product offering. We believe that future growth in unit sales will be derived both from a growth in the market for photocoagulator products and from the replacement of installed photocoagulators which use vacuum tube-based technology.

Our sales in the United States are derived from direct sales to end users and internationally are derived from sales to 54 distributors who resell to hospitals and physicians. 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, 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."

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:

	2000	1999	1998
	-----	-----	-----
Sales.....	100.0%	100.0%	100.0%
Cost of sales.....	43.8	44.2	43.8
	-----	-----	-----
Gross profit.....	56.2	55.8	56.2
	-----	-----	-----
Operating expenses:			
Research and development.....	15.7	14.6	13.1
Sales, general and administrative.....	32.2	34.4	35.4
	-----	-----	-----
Total operating expenses.....	47.9	49.0	48.5
	-----	-----	-----
Income from operations.....	8.3	6.8	7.7
Other income, net.....	1.7	2.0	2.2
	-----	-----	-----
Income before provision for income taxes.....	10.0	8.8	9.9
Provision for income taxes.....	(2.8)	(2.8)	(2.5)
	-----	-----	-----
Net income.....	7.2%	6.0%	7.4%
	=====	=====	=====

Sales. Sales were \$33.4 million in 2000, \$26.9 million in 1999 and \$23.6 million in 1998. These sales represented increases of 24.5% from 1999 to 2000 and 13.6% from 1998 to 1999. The increase in our sales in 2000 as compared to 1999 was due to increased unit volumes, primarily for sales of the OcuLight SLx and the OcuLight 664, offset in part by decreased average selling prices. The OcuLight 664 is a pre-commercialized activating laser sold to Miravant and Pharmacia for use in clinical studies. The increase in our sales in 1999 was due to increased unit volumes, primarily as a result of introduction of the Oculight GLx, and increased sales of the OcuLight SLx and DioLite, offset in part by decreased average selling prices, particularly with respect to our more mature products. International sales accounted for 35.6% of total sales in 2000, 38.4% in 1999 and 36.5% in 1998. International sales as a percentage of total sales decreased in 2000 from 1999 levels. The decrease is primarily due to decreased international sales of the DioLight 532, particularly in Japan, Canada and the Other Americas regions as a result of changes in the distribution channel for such products. We expect international sales as a percentage of total revenues for 2001 to be substantially equivalent to the 2000 rate. We expect future growth in sales to be primarily derived from sales of the OcuLight SLx, and the APEX 800 hair removal laser for dermatology, which we expect to introduce in the first half of 2001.

During July 2000, the Health Care Financing Administration (HCFA) advised that claims for reimbursement for certain AMD procedures that use our OcuLight SLx laser system would not be reimbursed by Medicare. In September 2000, HCFA changed its position and advised that claims for reimbursement for these AMD procedures can be submitted for reimbursement with coverage and payment to be determined by the local Medicare carriers at their discretion. As a result, since July 2000, sales of the OcuLight SLx laser system have dropped significantly. Sales of the OcuLight SLx continue, albeit at a lower level, because the OcuLight SLx can also be used for other ophthalmic procedures with Medicare reimbursement. Furthermore, since HCFA policies apply only to third party Medicare payors, 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 Medicare carriers elect to cover and reimburse for performing such AMD procedures or until HCFA advises that claims for these procedures are Medicare covered and reimburseable. We believe that more Medicare carriers will reimburse for these procedures or HCFA will allow national standardized reimbursement for them when they are further validated by clinical studies. The Company is supporting a randomized clinical trial to further validate Transpupillary Thermal Therapy, the most significant of the subject AMD procedures.

Sales into the research segment were \$0.6, \$0.5 and \$1.3 million for 2000, 1999 and 1998, respectively. Research sales increases in 2000 were nominal. International sales into the research segment were 35.8%,

33.0% and 21.4% for 2000, 1999 and 1998, respectively. Sales other than research segment sales are medical segment sales, which includes ophthalmology and dermatology sales.

**Gross Profit.** Gross profit was \$18.8 million in 2000, \$15.0 million in 1999 and \$13.3 million in 1998. Gross profit represented 56.2% of sales in 2000, 55.8% in 1999 and 56.2% in 1998. Gross profit as a percentage of sales increased slightly in 2000 as compared to 1999 due primarily to increased sales of OcuLight SLx systems, a high gross margin product. Such gross profit margin increases were offset in part by decreased sales of the DioLight 532, a high gross margin product, and lower average selling prices for the DioLight 532. Gross profit as a percentage of sales decreased in 1999 as compared to 1998 due primarily to lower average selling prices on most international product sales and first year sales of the OcuLight GLx, a lower margin product. Such gross profit margin decreases were offset in part by increased sales of the higher margin OcuLight SLx product. Moreover, increasing competition has continued to result in a downward trend in average selling prices for some products. 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. 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 mix of product sales, costs associated with future product introductions and a variety of other factors.

**Research and Development.** Research and development expenses increased by 34.1% in 2000 to \$5.3 million and by 26.7% in 1999 to \$3.9 million. These expenses were 15.7% of sales in 2000, 14.6% of sales in 1999 and 13.1% of sales in 1998. The increase in 2000 was primarily due to personnel and prototype expenses related to the development of the new Apex 800 hair removal dermatology system, development costs associated with unreleased ophthalmology products as well as increased clinical study costs. The increase in 1999 was primarily due to increased clinical study costs, such as our many Age-related Macular Degeneration (AMD) studies, personnel and prototype expenses related to the development of the new Apex 800 hair removal dermatology system and first year sustaining engineering costs for the OcuLight GLx. We expect these expenses for research and development to continue to increase in absolute dollars during 2001 in connection with new product development activities and clinical studies.

**Sales, General and Administrative.** Sales, general and administrative expenses increased by 16.5% in 2000 to \$10.7 million and by 10.4% in 1999 to \$9.2 million. These expenses were 32.2% of sales in 2000, 34.4% of sales in 1999 and 35.4% of sales in 1998. The increases in sales, general and administrative expenses in these periods, in absolute dollars, was primarily due to the hiring of additional sales and marketing employees to address new sales opportunities and to support expanding unit volumes, higher sales commissions and the growth in the infrastructure of our finance and administrative group which were necessary to support our expanded operations. In addition, we significantly expanded marketing operations and programs in 2000 in support of general ophthalmology and dermatology sales, as well as the new Apex 800 hair removal dermatology laser system. In 1999 significant costs were also associated with the communication of clinical results and the January 1999 launch of the OcuLight GLx.

**Other income, net.** Other income, net consists primarily of interest income. Interest income was \$552,000, \$469,000 and \$483,000 in 2000, 1999 and 1998, respectively. This income was primarily from interest earned on available-for-sale securities. Interest income increased in 2000 compared with 1999 because of higher interest rates and overall higher average cash balances during the year.

**Income Taxes.** We had an effective tax rate of 28%, 32% and 25% in 2000, 1999 and 1998, respectively. The tax rate for 2000, 1999 and 1998 was lower than the Federal and State combined statutory rate of 40% because of certain tax benefits associated with tax-exempt interest on tax preferred securities and with tax credits for research and experimental activities.

#### LIQUIDITY AND CAPITAL RESOURCES

At December 30, 2000, our primary sources of liquidity included cash and cash equivalents of \$10.0 million and available-for-sale securities of \$3.0 million, for a total of \$13.0 million. In addition, we have available \$2.0 million under our unsecured line of credit which bears interest at the bank's prime rate and

expires in October 2001. As of December 30, 2000, no borrowings were outstanding under this credit facility. We expect to renew the line of credit in October 2001 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 2001.

We generated \$353,000 in cash and cash equivalents during 2000. In 1999, we generated \$3,854,000 in cash and cash equivalents.

Net cash used in operations in 2000 totaled \$74,000 in 2000 as compared with \$2,862,000 generated from operations in 1999 and \$1,976,000 used in operations in 1998. In 2000, sources of cash included net income of \$2,416,000, depreciation of \$893,000, increases in accounts payable of \$280,000 and decreases in accounts receivable of \$165,000, offset by uses of cash from operations with increases in inventory, net, of \$2,465,000 and decreases in accrued expenses of \$1,014,000. In 1999, sources of cash from operations included net income of \$1,600,000, depreciation of \$721,000, increases in accrued expenses of \$2,420,000 and increases in accounts payable of \$249,000 partially offset by uses of cash from operations including increases of deferred income taxes of \$846,000, increases in inventory, net, of \$752,000 and increases in accounts receivable of \$623,000.

We used \$133,000 from investing activities in 2000. In 1999, we generated \$982,000 and in 1998 we used \$2,378,000 for investing activities. The generation or use was primarily due to the sale or purchase of available-for-sale securities and the acquisition of fixed assets.

Net cash provided by financing activities during 2000, 1999 and 1998 was \$560,000, \$10,000 and \$245,000, respectively, which consisted primarily of issuance of stock, offset in part by purchase of treasury stock of \$315,000 in 1999.

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. In 1999 we purchased 76,000 shares of our Common Stock from the open market. No shares were purchased during 2000.

#### RECENT ACCOUNTING PRONOUNCEMENTS

In June 1998, the Financial Accounting Standards Board issued SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities," which establishes accounting and reporting standards for derivative instruments and hedging activities. It requires that an entity recognize all derivatives as either assets or liabilities in the statement of financial position and measure those instruments at fair value. The Company, to date, has not engaged in derivative and hedging activities. The Company will adopt SFAS No. 133, as amended, in the first quarter of fiscal year 2001 and anticipates that the adoption will not have a material impact on the Company's financial statements.

#### FACTORS THAT MAY AFFECT FUTURE RESULTS

We Rely on Continued Market Acceptance of Our Products. We currently market visible and infrared light semiconductor-based photocoagulator medical laser systems to the ophthalmic market. We also market a visible light semiconductor-based photocoagulator medical laser system to the dermatology market. We believe that continued and increased sales, if any, of these medical laser systems is dependent upon the following factors:

- Product performance, procedures and price;
- Opinions of medical advisors and associates;
- Recommendations by ophthalmologists, dermatologists, clinicians, and their associated opinion leaders;

- Performance of these laser systems and treatments which are a beneficial alternative to competing technologies and treatments;
- The willingness of ophthalmologists and dermatologists to convert to semiconductor-based or infrared laser systems from visible argon gas or ion-based or other laser systems;
- The level of reimbursement for treatments administered with our products; and
- Our ability to introduce new products into these markets.

Any significant decline in market acceptance of our products would have a material adverse effect on our business, results of operations and financial condition.

Our Market is Competitive. Competition in the market for devices used for ophthalmic and dermatologic treatments is intense and is expected to increase. This market is also characterized by rapid technological innovation and change and our products could be rendered 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. Our principal competitors in ophthalmology are Coherent, Inc., Nidek, Inc. ("Nidek"), Carl Zeiss, Inc. ("Zeiss"), Alcon International, Quantel, and HGM Medical Laser Systems, Inc. ("HGM"). Of these companies, all currently offer a competitive, semiconductor-based laser system in ophthalmology. Our principal competitors in dermatology are Laserscope and HGM. The Apex 800 laser hair removal system will compete with products from Coherent, Inc., Candela Corporation, ESC Medical Systems, Ltd. and Cynosure, Inc. Some competitors have substantially greater financial, engineering, product development, manufacturing, marketing and technical resources than we do. Such companies also have greater name recognition than us and long-standing customer relationships. In addition to other companies that manufacture photocoagulators, we compete with pharmaceutical solutions, 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.

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. Completed systems must pass quality control and reliability tests before shipment. Although our OcuLight Systems and our DioLite 532 have been successfully introduced, we continue to face risks associated with manufacturing these products. Various difficulties may occur despite testing. Furthermore, we depend on third parties to manufacture substantially all of the components used in our products and have in the past experienced delays in manufacturing when a sole source supplier was unable to deliver components in volume and on a timely basis. Such a problem may recur. See "-- We Depend on Key Manufacturers and Suppliers." As a result of these factors, we may not be able to continue to manufacture our existing products or future products on a cost-effective and timely basis.

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, although we assemble critical subassemblies and the final product at our facility in Mountain View, California. Some of our 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 unavailability of or delays in obtaining adequate supplies of components, including optics, laser diodes, and crystals and potentially reduced control of quality, production costs and timing of delivery. We may experience difficulty identifying alternative sources of supply for certain components used in our products. In the past, we experienced delays in manufacturing the OcuLight GL due to the inability of a supplier to deliver components in volume and on a timely basis. We have qualified a second source for this laser diode component. The process of qualifying suppliers is ongoing and may be lengthy, particularly as new products are introduced. However, we have qualified two or more sources for most of the components used in our products. In addition, the use of alternate components may require design alterations which may delay installation and increase product costs. We have some long term or volume purchase agreements with our suppliers and currently purchase 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. Establishing our own capabilities to manufacture these components would be expensive and could significantly decrease our profit margins. Our business, results of operations and financial condition would be adversely affected if we are unable to continue to obtain components as required at a reasonable cost.

We Depend on International Sales. We derive and expect to continue to derive a large portion of our revenue from international sales. In 2000, 1999 and 1998, our international sales were \$11.9 million, \$10.3 million and \$8.6 million, or 35.6%, 38.4%, and 36.5%, respectively, of total sales. A large portion of our revenues will continue to be subject to the risks associated with international sales. These risks include currency fluctuations, 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. In general, strengthening of the U.S. dollar relative to a foreign currency increases the cost of our product to our customers. In 2000, for example, although we experienced revenue growth in Europe, competitive challenge from local suppliers was significant as a result of the weakness of the Euro against the U.S. dollar. Each of the factors stated above could have a material adverse effect on our ability to deliver products on a competitive and timely basis.

We Depend On Third Party Coverage and Reimbursement Policies. Our products are typically purchased by doctors, clinics, hospitals and other users, which bill various third-party payors, such as governmental programs and private insurance plans, for the health care services provided to their patients. Third-party payors carefully review and are increasingly challenging the prices charged for medical products and services. Reimbursement rates paid by third party payors may vary depending on the procedure performed, the third party payor, the insurance plan and other factors. Medicare reimburses hospitals on a prospectively determined fixed amount for the costs associated with an in-patient hospitalization based on the patient's discharge diagnosis. Medicare 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. Third-party payors are increasingly scrutinizing whether to cover 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 payors. While we believe that the laser procedures using our products have generally been reimbursed, payors 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 Health Care Financing Administration (HCFA) advised that claims for reimbursement for certain AMD procedures that use our OcuLight SLx laser system would not be reimbursed by Medicare. In September 2000, HCFA changed its position and advised that claims for reimbursement for these AMD procedures can be submitted for reimbursement, with coverage and payment to be determined by the local Medicare carriers at their discretion. As a result, since July 2000, sales of the OcuLight SLx laser system have dropped significantly. Sales of the OcuLight SLx continue, albeit at a lower level, because the OcuLight SLx can also be used for other ophthalmic procedures with Medicare reimbursement. Furthermore, since HCFA policies apply only to third party Medicare payors, 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 Medicare carriers elect to cover and reimburse for performing such AMD procedures or until HCFA advises that claims for these procedures are Medicare covered and reimbursable. We believe that more Medicare carriers will reimburse for these procedures or HCFA will allow national standardized reimbursement for them when they are further validated by clinical studies. The Company is supporting a randomized clinical trial to further validate Transpupillary Thermal Therapy, the most significant of the subject AMD procedures.

We have developed a new laser system with Miravant, the Oculight 664. Miravant may not be able to obtain coverage for its use of drugs with our OcuLight Systems, or the reimbursement may not be adequate to cover the treatment procedure. Changes in government legislation or regulation or in private third-party

payors' policies toward reimbursement for procedures employing our products may prohibit adequate reimbursement. Denial of coverage and reimbursement for our products could have a material adverse effect on our business, results of operations and financial condition. 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.

Most of the treatment procedures for dermatology using our DioLite 532 laser systems are billed to private-pay customers. Accordingly, reimbursement issues for our dermatology systems are insignificant.

Our Operating Results Fluctuate from Quarter to Quarter. Although we have been profitable on an annual and quarterly basis for the last eight years, our sales and operating results have varied substantially on a quarterly basis and may continue to do so 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:

- The timing of the introduction and market acceptance of new products, product enhancements and new applications, and their reimbursement;
- The cost and availability of components and subassemblies;
- Changes in our pricing and our competitors;
- Our long and highly variable sales cycle;
- Changes in customers' or potential customers' budgets; 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 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. As a result of the above factors, sales for any future quarter are not predictable with any significant degree of accuracy and operating results in any period should not be considered indicative of the results to be expected for any future period. There can be no assurance that we will remain profitable in the future or that operating results will not vary significantly.

We Depend on Development of New Products and New Applications. Our future success is dependent upon, among other factors, our ability to develop, obtain regulatory approval, manufacture and market new products. 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 efficacy of competing products, treatments and techniques and general economic conditions affecting purchasing patterns. Any failure in our ability to successfully develop and introduce new products or enhanced versions of existing products could have a material adverse effect on our business, operating results and financial condition. We are seeking to expand the market for our existing and new products by working with clinicians and third parties to identify new applications and procedures for our products. Failure to develop and achieve market acceptance of new applications or new products would have a material adverse effect on our business, results of operations and financial condition.

We Must Manage Growth. We have experienced, and may continue to experience growth in production, the number of employees, the scope of our business, our operating and financial systems and the geographic area of our operations. This growth has resulted in new and increased responsibilities for management personnel and our operating, inventory and financial systems. To effectively manage future growth, if any, we have been required to continue to implement and improve operational, financial and management information

systems, procedures and controls. In 1998 we implemented an enterprise-wide management information system. We must also expand, train, motivate and manage our work force. Our personnel, systems, procedures and controls may not be adequate to support our existing and future operations. Any failure to implement and improve our operational, financial and management systems or to expand, train, motivate or manage employees could have a material adverse effect on our business, results of operations and financial condition.

**We Depend on Collaborative Relationships.** We have entered into collaborative relationships with academic medical centers and physicians in connection with the research and development and clinical testing of our products. We plan to collaborate with third parties to develop and commercialize existing and new products. We are working with Miravant, formerly known as PDT, Inc., a maker of photodynamic drugs to collaborate on a device that emits a laser beam to activate a photodynamic drug developed by Miravant for the treatment of wet AMD. This collaborative development effort may not continue, or it may not result in the successful development and introduction of a photodynamic system, and the amount and timing of resources to be devoted to these activities are not within our control. Additionally, 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. 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.** 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 ten United States patents on the technologies related to our products and processes. Our patent applications may not issue as patents, any patents now or in the future may not offer any degree of protection, or our patents or patent applications may be challenged, invalidated or circumvented in the future. 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. Because patent applications are maintained in secrecy in the United States until patents are issued and are maintained in secrecy for a period of time outside the United States, we have not conducted any searches to determine whether our technology infringes any patents or patent applications. 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. This may adversely impact our operating results.

Any claims, with or without merit, could 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. Although patent and intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. An adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses 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.

**We Are Subject To Government Regulation.** The medical devices that we market and manufacture are subject to extensive regulation by the FDA and by foreign and state governments. Under the FDA 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 manufacturer must obtain market clearance through either the 510(k) premarket notification process or the lengthier premarket approval ("PMA") application process. Obtaining these approvals can take a long time and delay the introduction of a product. For example, the introduction of the OcuLight GL in the United States was delayed about three months from our expectations due to the longer than expected time period required to obtain FDA premarket clearance. Noncompliance with applicable requirements, including Quality System Regulations ("QSRs"), can result in, among other things, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the government to grant premarket clearance or premarket 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 we manufacture or distribute. 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.

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" registered, 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 registration under Annex II guidelines, the most stringent path to CE registration. With Annex II CE registration, IRIDEX Corporation has demonstrated its ability to both understand and comply with all applicable European standards. This allows us to register any product upon our internal verification of compliance to all applicable European Standards. Currently all released IRIS Medical and IRIDERM products are CE registered. Continued registration is based on successful review of the process by our European Registrar during their annual audit. Any loss of registration would have a material adverse effect on our business, results of operations and financial condition.

**We Face Product Liability Risks.** 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. In addition, although we recommend that our disposable products only be used once and so prominently label these disposables, we believe that certain customers may nevertheless reuse these disposable products. 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, our coverage from 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.

**Our Stock Price is Volatile.** The trading price of our Common Stock has been subject to wide fluctuations in response to a variety of factors since our initial public offering in February 1996. Volatility in price and volume has had a substantial effect on the market prices of many technology companies for reasons unrelated or disproportionate to the operating performance of such companies. These broad market fluctuations could have a significant impact on the market price of our Common Stock.

## 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 December 30, 2000.

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 exceed fiscal year 2001 and the interest rates are primarily fixed.

The following table presents the future principal cash flows or amounts and related weighted average interest rates expected by year for our existing cash and cash equivalents and marketable securities.

	2001 -----	TOTAL -----	FAIR VALUE -----
<b>ASSETS:</b>			
Cash, cash equivalents.....	\$9,998	\$9,998	\$9,998
Weighted average interest rate.....	4.05%	--	--
Short-term marketable securities.....	2,996	2,996	2,996
Weighted average interest rate.....	4.33%	--	--

## 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 its short- and long-term marketable securities portfolio.

Management evaluates our financial position on an ongoing basis.

**Currency Rate Risk**

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

## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated balance sheets as of December 30, 2000 and January 1, 2000 and the consolidated statements of income, comprehensive income, stockholders' equity and cash flows for each of the three years in the period ended December 30, 2000, together with the related notes and the report of PricewaterhouseCoopers LLP, independent accountants, are on the following pages. Additional required financial information is described in Item 14.

## REPORT OF INDEPENDENT ACCOUNTANTS

To the Board of Directors and Stockholders of IRIDEX Corporation:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of income, of stockholders' equity and of cash flows present fairly, in all material respects, the financial position of IRIDEX Corporation and its Subsidiaries (the "Company") at December 30, 2000 and January 1, 2000 and the results of their operations and their cash flows for each of the three years in the period ended December 30, 2000 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 accompanying index under 14(a)(2) on page 47 present fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. These consolidated financial statements and financial statement schedule are the responsibility of the Company's management; our responsibility is to express an opinion on these consolidated financial statements and financial statement schedules 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  
January 29, 2000

## IRIDEX CORPORATION

CONSOLIDATED BALANCE SHEETS  
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)

## ASSETS

	DECEMBER 30, 2000	JANUARY 1, 2000
	-----	-----
Current assets:		
Cash and cash equivalents.....	\$ 9,998	\$ 9,645
Available-for-sale securities.....	2,996	3,503
Accounts receivable, net of allowance for doubtful accounts of \$481 in 2000 and \$396 in 1999.....	8,010	8,260
Inventories, net.....	9,721	7,256
Prepays and other current assets.....	805	437
	-----	-----
Total current assets.....	31,530	29,101
Property and equipment, net.....	1,903	2,144
Deferred income taxes.....	1,592	1,518
	-----	-----
Total assets.....	\$35,025	\$32,763
	=====	=====

## LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable.....	\$ 1,408	\$ 1,128
Accrued expenses.....	3,117	4,131
	-----	-----
Total liabilities.....	4,525	5,259
	-----	-----
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: 6,700,862 shares in 2000 and 6,540,358 shares in 1999.....	67	66
Additional paid-in capital.....	22,691	22,124
Accumulated other comprehensive income (loss).....	10	(2)
Retained earnings.....	7,732	5,316
	-----	-----
Total stockholders' equity.....	30,500	27,504
	-----	-----
Total liabilities and stockholders' equity.....	\$35,025	\$32,763
	=====	=====

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

## IRIDEX CORPORATION

CONSOLIDATED STATEMENTS OF INCOME  
(IN THOUSANDS, EXCEPT PER SHARE DATA)

	YEAR ENDED DECEMBER 30, 2000	YEAR ENDED JANUARY 1, 2000	YEAR ENDED JANUARY 2, 1999
	-----	-----	-----
Sales.....	\$33,437	\$26,852	\$23,644
Cost of sales.....	14,638	11,878	10,367
	-----	-----	-----
Gross profit.....	18,799	14,974	13,277
	-----	-----	-----
Operating expenses:			
Research and development.....	5,265	3,925	3,099
Sales, general and administrative.....	10,747	9,224	8,358
	-----	-----	-----
Total operating expenses.....	16,012	13,149	11,457
	-----	-----	-----
Income from operations.....	2,787	1,825	1,820
Interest income.....	552	469	483
Other income, net.....	17	87	28
	-----	-----	-----
Income before provision for income taxes.....	3,356	2,381	2,331
Provision for income taxes.....	(940)	(763)	(583)
	-----	-----	-----
Net income.....	\$ 2,416	\$ 1,618	\$ 1,748
	=====	=====	=====
Net income per common share.....	\$ 0.36	\$ 0.25	\$ 0.27
	=====	=====	=====
Shares used in income per common share calculations.....	6,637	6,503	6,480
	=====	=====	=====
Diluted net income per common share.....	\$ 0.33	\$ 0.24	\$ 0.26
	=====	=====	=====
Shares used in diluted income per common share calculations.....	7,285	6,849	6,765
	=====	=====	=====

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	ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)	RETAINED EARNINGS	TOTAL
	SHARES	AMOUNT				
Balances, December 31, 1997.....	6,455,483	\$65	\$21,552	\$(2)	\$2,265	\$23,880
Issuance of Common Stock under Stock Option Plan.....	9,086		38			38
Issuance of Common Stock under Employee Stock Purchase Plan.....	41,441		204			204
Tax benefit of employee stock transactions.....			6			6
Change in unrealized gains on available-for-sale securities.....				9		9
Net income.....					1,748	1,748
Balances, January 2, 1999.....	6,506,010	65	21,800	7	4,013	25,885
Issuance of Common Stock under Stock Option Plan.....	51,544		107			107
Issuance of Common Stock under Employee Stock Purchase Plan.....	58,804	1	217			218
Purchase of Treasury Stock.....	(76,000)				(315)	(315)
Change in unrealized gains on available-for-sale securities.....				(9)		(9)
Net income.....					1,618	1,618
Balances, January 1, 2000.....	6,540,358	66	22,124	(2)	5,316	27,504
Issuance of Common Stock under Stock Option Plan.....	120,173	1	317			318
Issuance of Common Stock under Employee Stock Purchase Plan.....	40,331		242			242
Stock compensation expense.....			8			8
Change in unrealized gains on available-for-sale securities.....				12		12
Net income.....					2,416	2,416
Balances, December 30, 2000.....	6,700,862	\$67	\$22,691	\$10	\$7,732	\$30,500

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

## IRIDEX CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS  
(IN THOUSANDS)

	YEAR ENDED DECEMBER 30, 2000	YEAR ENDED JANUARY 1, 2000	YEAR ENDED JANUARY 2, 1999
	-----	-----	-----
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net income.....	\$ 2,416	\$ 1,618	\$ 1,748
Adjustments to reconcile net income to net cash provided by (used in) operating activities:			
Depreciation and amortization.....	893	721	653
Stock compensation expense.....	8	--	--
Provision for doubtful accounts.....	131	128	113
Provision for inventory.....	285	197	437
Deferred income taxes.....	(74)	(846)	(91)
Amortization of intangible asset.....	--	96	--
Changes in operating assets and liabilities:			
Accounts receivable.....	119	(682)	(1,664)
Inventories.....	(2,750)	(949)	(2,965)
Prepays and other current assets.....	(368)	(90)	104
Accounts payable.....	280	249	127
Accrued expenses.....	(1,014)	2,420	(438)
	-----	-----	-----
Net cash provided by (used in) operating activities.....	(74)	2,862	(1,976)
	-----	-----	-----
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchases of available-for-sale securities.....	(3,856)	(3,511)	(7,675)
Proceeds from sale and maturity of available-for-sale securities.....	4,375	5,084	6,187
Acquisition of property and equipment.....	(652)	(591)	(794)
Acquisition of intangible assets.....	--	--	(96)
	-----	-----	-----
Net cash provided by (used in) investing activities.....	(133)	982	(2,378)
	-----	-----	-----
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Payments of capital lease obligations.....	--	--	(3)
Purchase of Treasury Stock.....	--	(315)	--
Issuance of Common Stock under stock option plans.....	560	325	248
	-----	-----	-----
Net cash provided by financing activities.....	560	10	245
	-----	-----	-----
Net (decrease) increase in cash and cash equivalents.....	353	3,854	(4,109)
Cash and cash equivalents, beginning of year.....	9,645	5,791	9,900
	-----	-----	-----
Cash and cash equivalents, end of year.....	\$ 9,998	\$ 9,645	\$ 5,791
	=====	=====	=====
<b>SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:</b>			
Cash paid during the period for:			
Income taxes.....	2,244	360	575
<b>SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING ACTIVITIES:</b>			
Change in unrealized gains (losses) on available-for-sale securities.....	\$ 12	\$ (9)	\$ 9

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

IRIDEX CORPORATION  
 CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME  
 (IN THOUSANDS)

	YEAR ENDED DECEMBER 30, 2000 -----	YEAR ENDED JANUARY 1, 2000 -----	YEAR ENDED JANUARY 2, 1999 -----
Net income.....	\$2,416	\$1,618	\$1,748
Other comprehensive income:			
Changes in unrealized gain (loss) on Available-for-sale securities.....	12	(9)	9
	-----	-----	-----
Comprehensive income.....	\$2,428	\$1,609	\$1,757
	=====	=====	=====

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 the 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 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 risks.

## Available-for-Sale Securities

All marketable securities as of December 30, 2000 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 acquired under capital lease obligations is computed using the straight-line method over the shorter of the remaining lease term or the estimated useful life of the related assets, typically three years.

## Revenue Recognition

The Company has adopted the provisions of Staff Accounting Bulletin ("SAB") No. 101 "Revenue Recognition in Financial Statements" and believes that its current and historical revenue recognition policy is in compliance with the SAB. The Company has also applied Emerging Issues Task Force Issue No. ("EITF") 00-10 "Accounting for Shipping and Handling Fees and Costs" retroactively to all periods presented. As a result, for all periods presented, amounts billed to customers relating to shipping and handling have been classified as revenue and all related costs are classified as cost of sales.

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. Up-front fees

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

received in connection with product sales are deferred and recognized over the associated product shipments. 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.

#### 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 2000, 1999 and 1998 were \$478,000, \$359,000 and \$317,000, respectively.

#### Fair Value of Financial Instruments

SFAS 107, "Disclosure About Fair Value of Financial Instruments" requires certain disclosure regarding the 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 values due to their short maturities. Estimated fair values for available-for-sale securities, which are separately disclosed elsewhere, are based on quoted market prices for the same or similar instruments.

#### Income Taxes

Income taxes are accounted for under Statement of Financial Accounting Standards (SFAS) No. 109, "Accounting for Income Taxes." Under SFAS No. 109, 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 No. 25, "Accounting for Stock Issued to Employees" ("APB 25") and complies with the disclosure provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("SFAS 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 in Note 6.

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 Good and Services," and Financial Accounting Standards Board Interpretation No. 28, "Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plan" ("FIN 28").

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

## 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 December 30, 2000 and January 1, 2000 no customer accounted for greater than 10% of revenue. As of December 30, 2000 and January 1, 2000 no customer accounted for greater 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 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

Management makes estimates and assumptions to prepare the consolidated financial statements in conformity with generally accepted accounting principles. These estimates and assumptions affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

## Reclassification

Certain prior year amounts have been reclassified to conform to the current year's presentation.

## Fiscal Year

On June 8, 1998, the Board of Directors approved a resolution to adjust our fiscal year end from December 31 to the 52 or 53-week period that ends the Saturday nearest December 31, effective for fiscal year 1998, a 52-week year. Fiscal year 2000 and fiscal 1999 included 52-weeks.

## Net Income per Share

Basic and diluted net income per share are computed by dividing net income for the period by the weighted average number of shares of common stock outstanding during the period. The calculation of diluted net income 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.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

## Recent Accounting Pronouncements

In June 1998, the Financial Accounting Standards Board issued SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities," which establishes accounting and reporting standards for derivative instruments and hedging activities. It requires that an entity recognize all derivatives as either assets or liabilities in the statement of financial position and measure those instruments at fair value. The Company, to date, has not engaged in derivative and hedging activities. The Company will adopt SFAS No. 133, as amended, in the first quarter of fiscal year 2001 and anticipates that the initial adoption will not have a material impact on the Company's financial statements.

## 3. BALANCE SHEET DETAIL

## Available-for-Sale Securities (in thousands):

	COST	UNREALIZED GAINS (LOSSES)	ESTIMATED FAIR VALUE	MATURITY DATES
	-----	-----	-----	-----
As of December 30, 2000, available-for-sale securities consisted of the following:				
Government agencies.....	2,986	10	2,996	2/01 - 7/01
As of January 1, 2000, available-for-sale securities consisted of the following:				
Corporate notes.....	\$2,550	\$--	\$2,550	1/00 - 5/00
Government agencies.....	955	(2)	953	5/00
	-----	-----	-----	
	\$3,505	\$(2)	\$3,503	
	=====	===	=====	

There were no realized capital gains or losses recognized in 2000, 1999 and 1998.

	DECEMBER 30, 2000	JANUARY 1, 2000
	-----	-----
	(IN THOUSANDS)	
Inventories:		
Raw materials and work in process.....	\$ 6,168	\$ 3,839
Finished goods.....	3,553	3,417
	-----	-----
Total inventories.....	\$ 9,721	\$ 7,256
	=====	=====
Property and Equipment:		
Equipment.....	\$ 3,229	\$ 2,667
Leasehold improvements.....	1,829	1,739
Less: accumulated depreciation and amortization.....	(3,155)	(2,262)
	-----	-----
Property and equipment, net.....	\$ 1,903	\$ 2,144
	=====	=====
Accrued Expenses:		
Accrued payroll, vacation and related expenses.....	\$ 1,057	\$ 1,102
Accrued warranty.....	728	536
Income taxes payable.....	404	1,621
Sales and use tax payable.....	195	207
Other accrued expenses.....	733	665
	-----	-----
Total accrued expenses.....	\$ 3,117	\$ 4,131
	=====	=====

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

## 4. BANK BORROWINGS

We have a revolving line of credit agreement with a bank expiring on October 1, 2001, which provides for borrowings of up to \$2.0 million at the bank's prime rate (9.5% at December 30, 2000). The agreement contains restrictive covenants including prohibiting payment of dividends without the bank's prior consent. There were no borrowings against the credit line at December 30, 2000. We intend to renew the line of credit in October 2001 assuming that terms continue to be acceptable.

## 5. COMMITMENTS AND CONTINGENCIES

## Lease Agreements

We lease our operating facilities under a noncancelable operating lease. The lease expires in 2002 and contains renewal options. Rent expense, net of sublease income, totaled \$289,000, \$282,000 and \$331,000 for the years ended December 30, 2000, January 1, 2000 and January 2, 1999 respectively. Rental income related to a facility sublease was \$262,000, \$183,000 and \$182,000 for the years ended December 30, 2000, January 1, 2000 and January 2, 1999, respectively.

Future minimum lease payments and income under current operating leases at December 30, 2000 are summarized as follows (in thousands):

FISCAL YEAR	OPERATING LEASE PAYMENTS	SUBLEASE INCOME	NET OPERATING LEASE PAYMENTS
-----	-----	-----	-----
2001	554	11	543
2002	93	--	93
	----	---	----
	\$647	\$11	\$636
	====	===	====

## License Agreements

The Company is obligated to pay royalties equivalent to 4% and 7.5% of sales on certain products under certain license agreements. Royalty expense was \$21,000, \$42,000 and \$125,000 for the years ended December 30, 2000, January 1, 2000 and January 2, 1999, 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.

## 6. STOCKHOLDERS' EQUITY

## CONVERTIBLE PREFERRED STOCK

During 1996, we amended our Articles of Incorporation to authorize 2,000,000 shares of undesignated preferred stock. Preferred Stock may be issued from time to time in one or more series. As of December 30, 2000, 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 program. We repurchased 76,000 shares of Common Stock for \$315,000 in 1999.



## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

## 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. The form of consideration for exercising an option or stock purchase right, including the method of payment, is determined by the Administrator. The 1998 Plan expires in June 2008.

## 1995 Director Option Plan

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

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

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. On April 28, 1997, the shareholders approved an amendment to increase the total number of

## IRIDEX CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

shares of common stock for issuance under the Purchase Plan from 50,000 to 100,000. 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):

	SHARES AVAILABLE FOR GRANT	OUTSTANDING OPTIONS NUMBER OF SHARES	AGGREGATE PRICE	WEIGHTED AVERAGE EXERCISE PRICE
	-----	-----	-----	-----
Balances, December 31, 1997.....	243,559	961,787	\$ 4,860	\$5.05
Additional shares reserved.....	310,000	--	--	--
Options granted at market price.....	(936,889)	936,889	4,628	4.94
Options exercised.....		(9,101)	(38)	4.18
Options terminated.....	572,074	(572,074)	(4,031)	7.05
	-----	-----	-----	-----
Balances, January 2, 1999.....	188,744	1,317,501	5,419	4.11
Additional shares reserved.....	150,000	--	--	--
Options granted at market price.....	(218,394)	218,394	1,128	5.16
Options exercised.....		(47,568)	(107)	1.89
Options expired.....	(11,819)			
Options terminated.....	81,134	(81,134)	(364)	4.45
	-----	-----	-----	-----
Balances, January 1, 2000.....	189,665	1,407,193	6,076	4.31
	-----	-----	-----	-----
Additional shares reserved.....	260,000	--	--	--
Options granted at market price.....	(384,700)	384,700	3,570	9.28
Options exercised.....		(120,173)	(318)	2.64
Options expired.....	(82,560)			
Options terminated.....	181,407	(181,407)	(1,036)	5.71
	-----	-----	-----	-----
Balances, December 30, 2000.....	163,812	1,490,313	\$ 8,292	\$5.56
	=====	=====	=====	

In December 1998, we offered non-executive officer employees the right to cancel certain outstanding Stock Options and receive new options with an exercise price of \$4.00 per share, the closing price of the common stock on the date individual employees agreed to cancel their original outstanding stock options. Options to purchase a total of 548,000 shares at original exercise prices ranging from \$5.00 to \$14.75 per share were canceled and new options were issued in December 1998. Under the terms of this offer, new options were subject to new vesting terms from the date of issuance.

## IRIDEX CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

The following table summarizes information with respect to stock options outstanding at December 30, 2000:

RANGE OF EXERCISE PRICES	OPTIONS OUTSTANDING			OPTIONS EXERCISABLE	
	NUMBER OUTSTANDING AT 12/30/00	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE (YEARS)	WEIGHTED AVERAGE EXERCISE PRICE	NUMBER EXERCISABLE AT 12/30/00	WEIGHTED AVERAGE EXERCISE PRICE
\$ 0.16 - \$ 0.16	13,791	1.11	\$ 0.16	13,791	\$ 0.16
\$ 1.00 - \$ 1.00	136,830	3.71	1.00	136,830	1.00
\$ 2.00 - \$ 2.00	51,750	4.80	2.00	51,750	2.00
\$ 3.93 - \$ 5.75	779,942	7.14	4.35	432,246	4.41
\$ 6.25 - \$ 9.25	420,000	8.20	8.69	115,896	8.21
\$ 9.50 - \$13.62	76,750	9.59	11.52	360	12.75
\$14.88 - \$14.88	11,250	5.50	14.88	11,250	14.88
	-----		-----	-----	-----
\$ 0.16 - \$14.88	1,490,313		5.56	762,123	4.29
	=====			=====	

At January 1, 2000 and January 2, 1999 options to purchase 624,025 and 393,046 shares of Common Stock were exercisable at weighted average exercise prices of \$3.53 and \$2.43, respectively.

The following information concerning our stock option and employee stock purchase plans is provided in accordance with SFAS No. 123, "Accounting for Stock-Based Compensation." We account for such plans in accordance with Accounting Principles Board No. 25 and related Interpretations.

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:

	2000		1999		1998	
	GROUP A	GROUP B	GROUP A	GROUP B	GROUP A	GROUP B
Risk-free Interest Rates.....	6.00%	6.19%	5.58%	5.34%	4.82%	4.79%
Expected Life from Date of Vesting.....	3 yrs...	2 yrs.	3 yrs.	2 yrs.	3 yrs.	2 yrs.
Volatility.....	0.78	0.78	0.78	0.78	0.78	0.78
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 2000, 1999 and 1998 was \$5.96, \$3.37 and \$3.12, respectively.

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 1999, 1998 and 1997:

	2000	1999	1998
Risk-free Interest Rates.....	5.67%	4.91%	5.61%
Expected Life.....	0.5 year	0.5 year	0.5 year
Volatility.....	0.78	0.78	0.78
Dividend Yield.....	--	--	--

The weighted average grant-date fair value per share of those purchase rights granted in 2000, 1999 and 1998 was \$2.94, \$1.55 and \$3.33, respectively.



## IRIDEX CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

The following pro forma income information has been prepared following the provisions of SFAS No. 123:

	2000	1999	1998
	-----	-----	-----
	(AMOUNTS IN THOUSANDS EXCEPT PER SHARE DATA)		
Net income -- as reported.....	\$2,416	\$1,618	\$1,748
Net income -- pro forma.....	\$1,640	\$ 768	\$ 815
Net income per common share -- as reported.....	\$ 0.36	\$ 0.25	\$ 0.27
Net income per common share -- pro forma.....	\$ 0.25	\$ 0.12	\$ 0.13
Diluted net income per common share -- as reported.....	\$ 0.33	\$ 0.24	\$ 0.26
Diluted net income per common share -- pro forma.....	\$ 0.22	\$ 0.11	\$ 0.12

## 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. Company contributions in fiscal 2000 totaled \$64,000. No contributions were made in fiscal 1999 or fiscal 1998.

## 8. INCOME TAXES

The provision for income taxes includes:

	YEAR ENDED DECEMBER 30, 2000	YEAR ENDED JANUARY 1, 2000	YEAR ENDED JANUARY 2, 1999
	-----	-----	-----
	(IN THOUSANDS)		
Current:			
Federal.....	\$ 986	\$1,323	\$425
State.....	28	286	67
	1,014	1,609	492
Deferred:			
Federal.....	(96)	(613)	105
State.....	22	(233)	(14)
	-----	-----	-----
	(74)	(846)	(91)
	-----	-----	-----
Income tax provision.....	\$ 940	\$ 763	\$583
	=====	=====	=====

## IRIDEX CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

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

	YEAR ENDED DECEMBER 30, 2000	YEAR ENDED JANUARY 1, 2000	YEAR ENDED JANUARY 2, 1999
	-----	-----	-----
	(IN THOUSANDS)		
Income tax provision at statutory rate.....	34%	34%	34%
State income taxes, net of federal benefit.....	6%	6%	3%
Tax exempt interest.....	(3)%	(3)%	(5)%
Research and experimental credits.....	(10)%	(10)%	(5)%
Other.....	1%	5%	(2)%
	---	---	--
Effective tax rate.....	28%	32%	25%
	===	===	==

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

	DECEMBER 30, 2000	JANUARY 1, 2000
	-----	-----
Fixed assets.....	\$ 487	\$ 464
Accrued liabilities.....	467	436
Allowance for excess and obsolete inventories.....	151	147
Research credit.....	329	116
State tax.....	--	47
Allowance for doubtful accounts.....	186	194
Other.....	(28)	114
	-----	-----
Net deferred tax asset.....	\$1,592	\$1,518
	=====	=====

## 9. MAJOR CUSTOMERS AND BUSINESS SEGMENTS

We operate in two reportable segments: the laser medical device segment and the laser research segment. In the laser medical device segment, we develop, manufacture and market medical devices for the ophthalmology and dermatology markets. Our revenues arise from the sale of consoles, delivery devices, disposables and service and support activities. In the laser research segment we conduct research and development under research grants from the U.S. Federal Government and others. Under the terms of these grants we typically retain the right to commercially market the technology developed.

In the years ended December 30, 2000, January 1, 2000 and January 2, 1999, no customer individually accounted for more than 10% of our revenue.

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

	DECEMBER 30, 2000	JANUARY 1, 2000	JANUARY 2, 1999
	-----	-----	-----
United States.....	\$21,549	\$16,533	\$15,017
Europe.....	5,658	4,673	4,503
Rest of Americas.....	1,283	1,689	1,552
Asia/Pacific Rim.....	4,947	3,957	2,572
	-----	-----	-----
	\$33,437	\$26,852	\$23,644
	=====	=====	=====

Revenues are attributed to countries based on location of customers.

## IRIDEX CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

In the years ended December 30, 2000, January 1, 2000 and January 2, 1999, no country individually accounted for more than 10% of our sales, except for the United States, which accounted for 64.4 % of sales in 2000, 61.6% in 1999 and 63.5% in 1998.

Information on reportable segments for the three years ended December 30, 2000, January 1, 2000 and January 2, 1999 is as follows:

	YEAR ENDED DECEMBER 30, 2000		YEAR ENDED JANUARY 1, 2000		YEAR ENDED JANUARY 2, 1999	
	LASER MEDICAL DEVICES	LASER RESEARCH	LASER MEDICAL DEVICES	LASER RESEARCH	LASER MEDICAL DEVICES	LASER RESEARCH
Sales.....	\$32,838	\$599	\$26,392	\$460	\$22,339	\$1,305
Depreciation and amortization.....	881	12	705	16	627	26
Interest income.....	552	--	469	--	483	--
Income before provision for income taxes.....	2,901	455	2,146	235	1,504	827

Income before provision for income taxes of the laser research segment does not include indirect costs of manufacturing, research and development and selling, general and administrative costs. Such costs are not allocated and therefore are included in the Laser Medical Device segment.

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 per common share and diluted net income per common share is provided as follows (in thousands, except per share amounts):

	YEAR ENDED DECEMBER 30, 2000	YEAR ENDED JANUARY 1, 2000	YEAR ENDED JANUARY 2, 1999
Numerator -- Net income per common share and per diluted common share			
Net income.....	\$2,416	\$1,618	\$1,748
Denominator -- Net income per common share			
Weighted average common stock outstanding.....	6,637	6,503	6,480
Net income per common share.....	\$ 0.36	\$ 0.25	\$ 0.27
Denominator -- Diluted net income per common share			
Weighted average common stock outstanding.....	6,637	6,503	6,480
Effect of dilutive securities			
Weighted average common stock options.....	648	346	285
Total weighted average stock and options outstanding....	7,285	6,849	6,765
Diluted net income per common share.....	\$ 0.33	\$ 0.24	\$ 0.26

During 2000, 1999 and 1998, there were 62,930, 431,077, and 300,500 outstanding options to purchase shares, respectively, at a weighted average exercise price of \$9.82, \$5.28, and \$7.69 per share, respectively, were not included in the computations of diluted net income per common share since, in each, case the exercise price of the common shares exceeded the market price of the related options.

## IRIDEX CORPORATION

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

## 11. SELECTED QUARTERLY FINANCIAL DATA, (UNAUDITED)

	QUARTER			
	FIRST	SECOND	THIRD	FOURTH
	(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)			
Year Ended December 30, 2000				
Sales (revised)(1).....	\$8,215	\$8,808	\$8,520	\$7,894
Sales (as previously reported)(1).....	\$8,192	\$8,785	\$8,498	\$7,962
Gross profit.....	\$4,810	\$5,103	\$4,680	\$4,206
Net income.....	\$ 711	\$ 716	\$ 561	\$ 428
Net income per common share.....	\$ 0.11	\$ 0.11	\$ 0.08	\$ 0.06
Diluted net income per common share.....	\$ 0.09	\$ 0.10	\$ 0.08	\$ 0.06
Year Ended January 1, 2000				
Sales (revised)(1).....	\$5,715	\$6,485	\$6,317	\$8,335
Sales (as previously reported)(1).....	\$5,697	\$6,463	\$6,295	\$8,307
Gross profit.....	\$3,081	\$3,552	\$3,524	\$4,817
Net income.....	\$ 185	\$ 325	\$ 325	\$ 783
Net income per common share.....	\$ 0.03	\$ 0.05	\$ 0.05	\$ 0.12
Diluted net income per common share.....	\$ 0.03	\$ 0.05	\$ 0.05	\$ 0.11

(1) Sales and cost of sales figures have been revised as a result of the retroactive adoption of EITF 00-10 "Accounting for Shipping and Handling Fees and Costs."



## ITEM 9. DISAGREEMENTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

## PART III

Certain information required by Part III has been omitted from this Form 10-K. This information is instead incorporated by reference to our definitive proxy statement (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 6, 2001.

## ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

Information regarding our directors is incorporated by reference to "Election of Directors -- Nominees" in our Proxy Statement for the Company's 2000 Annual Meeting of Stockholders. The information concerning our current executive officers is found under the caption "Executive Officers of the Registrant" in Part I hereof is also incorporated by reference into this Item 10.

## ITEM 11. EXECUTIVE COMPENSATION

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

## ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

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

## PART IV

## ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

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

	PAGE IN FORM 10-K REPORT -----
1. FINANCIAL STATEMENTS	
Report of Independent Accountants.....	28
Consolidated Balance Sheets as of December 30, 2000 and January 1, 2000.....	29
Consolidated Statements of Income for the years ended December 30, 2000, January 1, 2000 and January 2, 1999.....	30
Consolidated Statements of Stockholders' Equity for the years ended December 30, 2000, January 1, 2000 and January 2, 1999.....	31
Consolidated Statements of Cash Flows for the years ended December 30, 2000, January 1, 2000 and January 2, 1999.....	32
Consolidated Statements of Comprehensive Income for the years ended December 30, 2000, January 1, 2000 and January 2, 1999.....	33
Notes to Consolidated Financial Statements.....	34
2. FINANCIAL STATEMENT SCHEDULE	
The following financial statement schedule is included in Item 14(d):	
Schedule II - Valuation and Qualifying Accounts.....	50

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(3)	Amended and Restated Bylaws of Registrant.
10.1(1)	Form of Indemnification Agreement with directors and officers.
10.2(1)	Amended and Restated 1989 Incentive Stock Plan and form of agreement thereunder.
10.3(1)	1995 Employee Stock Purchase Plan, as amended and form of agreement thereunder.
10.4(1)	1995 Director Option Plan and form of agreement thereunder.
10.5(1)	1995 Profit Sharing Plan.
10.6(1)	Third Restated Registration Rights Agreement dated as of October 27, 1995 by and among Registrant and certain individuals and entities named therein.
10.7(1)	Lease Agreement dated December 6, 1996 by and between Zappettini Investment Co. and the Registrant.
10.8(1)	Business Loan Agreement dated October 4, 1995 between Mid-Peninsula Bank and the Registrant.
10.9(4)	1998 Stock Option Plan, as amended.
10.10(2)*	Development and Distribution Agreement dated as of May 28, 1996 between Miravant, Inc. (formerly PDT, Inc.) and the Company.
21.1(1)	Subsidiaries of Registrant.
23.1	Consent of Independent Accountants.
24.1	Power of Attorney (See page 49).

-----  
\* Confidential treatment has been granted with respect to certain portions of this exhibit.

- (1) Incorporated by reference to the like-numbered 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 June 30, 1996.
  - (3) Incorporated by reference to the Exhibits in Registrant's Report on Form 10-Q for the quarter ended October 3, 1998.
  - (4) 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.
- (b) REPORTS ON FORM 8-K

We filed a Current Report on Form 8-K on December 7, 2000 with the Securities and Exchange Commission to report the issuance of a press release announcing lower than expected earnings for our fourth fiscal quarter of 2000.

#### TRADEMARK ACKNOWLEDGMENTS

IRIDEX, the IRIDEX logo, IRIS Medical, OcuLight, SmartKey, and EndoProbe are our registered trademarks. IRIDERM, G-Probe, DioPexy, DioVet, TruFocus, TrueCW, UltraView and DioLite 532 product names are our trademarks. All other trademarks or trade names appearing in the Form 10-K are the property of their respective owners.

## 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 the 30th day of March, 2001.

## 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 Robert Kamenski, 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 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, of 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.

NAME -----	TITLE -----	DATE -----
/s/ THEODORE A. BOUTACOFF ----- (Theodore A. Boutacoff)	President, Chief Executive Officer, and Director (Principal Executive Officer)	March 30, 2001
/s/ ROBERT KAMENSKI ----- (Robert Kamenski)	Chief Financial Officer and Vice President, Administration (Principal Financial and Accounting Officer)	March 30, 2001
/s/ JAMES L. DONOVAN ----- (James L. Donovan)	Vice President, Corporate Business Development and Director	March 30, 2001
/s/ ROBERT K. ANDERSON ----- (Robert K. Anderson)	Director	March 30, 2001
/s/ WILLIAM BOEGER, III ----- (William Boeger, III)	Director	March 30, 2001
/s/ DONALD L. HAMMOND ----- (Donald L. Hammond)	Director	March 30, 2001
/s/ JOSHUA MAKOWER ----- (Joshua Makower)	Director	March 30, 2001
/s/ JOHN M. NEHRA ----- (John M. Nehra)	Chairman of the Board	March 30, 2001

## SCHEDULE II

## IRIDEX CORPORATION AND SUBSIDIARIES

VALUATION AND QUALIFYING ACCOUNTS  
(IN THOUSANDS)

DESCRIPTION -----	BALANCE AT BEGINNING OF THE PERIOD -----	CHARGED TO COSTS AND EXPENSES -----	DEDUCTIONS -----	BALANCE AT END OF THE PERIOD -----
Balance for the year ended January 2, 1999:				
Allowance for doubtful accounts receivable.....	\$305	\$113	\$ (91)	\$327
Provision for inventory.....	\$ --	\$437	\$(253)	\$182
Balance for the year ended January 1, 2000:				
Allowance for doubtful accounts receivable.....	\$327	\$128	\$ (59)	\$396
Provision for inventory.....	\$182	\$197	\$ (5)	\$374
Balance for the year ended December 30, 2000:				
Allowance for doubtful accounts receivable.....	\$396	\$131	\$ (46)	\$481
Provision for inventory.....	\$374	\$285	\$ --	\$659

## EXHIBIT INDEX

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- (3) Incorporated by reference to the Exhibits in Registrant's Report on Form 10-Q for the quarter ended October 3, 1998.
- (4) 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.

## CONSENT OF INDEPENDENT ACCOUNTANTS

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-45736) of IRIDEX Corporation of our report dated January 29, 2001 relating to the consolidated financial statements and financial statement schedule, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

San Jose, California  
March 30, 2001