

Edgar Filing: IRIDEX CORP - Form 10-K405

IRIDEX CORP
Form 10-K405
March 29, 2002

=====

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON D.C. 20549

FORM 10-K

- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934
FOR THE FISCAL YEAR ENDED DECEMBER 29, 2001
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934
FOR THE TRANSITION PERIOD FROM _____ TO _____.

COMMISSION FILE NUMBER 0-27598

IRIDEX CORPORATION
(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

DELAWARE
(STATE OR OTHER JURISDICTION
OF INCORPORATION OR ORGANIZATION)

77-0210467
(I.R.S. EMPLOYER
IDENTIFICATION NUMBER)

1212 TERRA BELLA AVENUE, MOUNTAIN VIEW CA 94043-1824
(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES)
(ZIP CODE)
(650) 940-4700
(REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE)

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:
NONE

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT:
COMMON STOCK, \$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, 2002, was approximately \$14,703,055 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

Edgar Filing: IRIDEX CORP - Form 10-K405

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, 2002, Registrant had 6,862,862 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain parts of the Proxy Statement for the Registrant's 2002 Annual Meeting of Stockholders (the "Proxy Statement") are incorporated by reference into Part III of this Annual Report on Form 10-K.

=====

Table of Contents

Part I

| | | |
|---------|--|-------|
| Item 1. | Business..... | |
| Item 2. | Properties..... | |
| Item 3. | Legal Proceedings..... | |
| Item 4. | Submission of Matters to a Vote of Security Holders..... | |

Part II

| | | |
|----------|--|-------|
| Item 5. | Market for Registrants' Common Equity and Related Stockholder Matters..... | |
| Item 6. | Selected Financial Data..... | |
| Item 7. | Management's Discussion and Analysis of Financial Condition and Results of Operations..... | |
| Item 7A. | Quantitative and Qualitative Disclosure about Market Risk..... | |
| Item 8. | Financial Statements and Supplementary Data..... | |
| Item 9. | Disagreements on Accounting and Financial Disclosure..... | |

Part III

| | | |
|----------|---|-------|
| Item 10. | Directors and Executive Officers of the Registrant..... | |
| Item 11. | Executive Compensation..... | |
| Item 12. | Security Ownership of Certain Beneficial Owners and Management..... | |
| Item 13. | Certain Relationships and Related Transactions..... | |

Part IV

| | | |
|----------|--|-------|
| Item 14. | Exhibits, Financial Statement Schedules and Reports on Form 8-K..... | |
|----------|--|-------|

| | | |
|-----------------|-------|-------|
| Signatures..... | | |
|-----------------|-------|-------|

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 sales and operating results, including sales of our OcuLight SLx and Apex 800 laser systems; actual order rate and market acceptance of our products, opportunities in the adjunctive diagnostic market and our efforts to provide total disease management solutions; expectations for future

Edgar Filing: IRIDEX CORP - Form 10-K405

sales growth, generally, and the potential for production cost decreases and higher gross margins; our estimates of the size of our markets; levels of future investment in research and development; the development of new, more cost-effective technologies, therapeutic and adjunctive diagnostic systems, strategic alliances and new delivery devices; favorable Center for Medicare and Medicaid coverage decisions regarding AMD procedures that use our products; results of clinical studies and risks associated with bringing new products to market, general economic conditions and levels of international sales. In some cases, forward-looking statements can be identified by terminology, such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "intends," "potential," "continue," or the negative of such terms or other comparable terminology. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to differ materially from those expressed or implied by such forward-looking statements. 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. We undertake no obligation to update the results of any revision of these forward-looking statements. The reader is strongly urged to read the information set forth under the caption "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 is a leading worldwide provider of semiconductor-based laser systems used to treat eye diseases in ophthalmology and skin afflictions in dermatology (also referred to as aesthetics). Our products are sold in the United States predominantly through a direct sales force and internationally through 67 independent distributors into 91 countries.

Our ophthalmology products treat eye diseases, including the three leading causes of irreversible blindness. Our current family of OcuLight laser systems, used for ophthalmic applications, includes the IRIS Medical OcuLight SL, OcuLight SLx, OcuLight GL and OcuLight GLx Laser Photocoagulation systems. Our dermatology products treat skin diseases, primarily vascular and pigmented lesions and remove unwanted hair. The dermatology laser systems that we offer include the IRIDERM DioLite 532 and the Apex 800 systems. Our revenues arise primarily from the sale of these OcuLight laser systems used in treatment of various eye diseases and the DioLite 532 and Apex 800 used for dermatological applications. 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. Since our first shipment in 1990, more than 4,900 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

Edgar Filing: IRIDEX CORP - Form 10-K405

"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. One of our core strengths has been our regular introduction of new laser systems, delivery devices and product upgrades to enhance the benefits of our laser systems. We attempt to leverage our existing products and technology when developing new products. In 1997, we introduced the DioLite 532, based on the same visible light technology as the OcuLight GL, for the dermatology market. In 1998, we introduced the OcuLight GLx, a new version of the OcuLight GL, with increased power and delivery device capability. In October 1999, we introduced the next generation of OcuLight SLx, which offers added features, such as LongPulse and MicroPulse operating modes. These features enable the OcuLight SLx to perform the latest in clinical infrared applications. In October 2000, we introduced the Easy Fit family of portable slit lamp adapters (SLAs). These new SLAs allow for improved viewing clarity of the retina by the physician. In 2001, we introduced the Apex 800, a high powered infrared laser for hair removal for the dermatology market. The characteristics of these products are similar to those which have made our previous products successful, such as low cost ownership, reliability and portability. We intend to continue our investment in research and development to improve the performance of our systems. We also intend to develop additional technologies which can more cost effectively address the needs of the ophthalmic and dermatologic markets.

Develop and Validate New Applications. We seek to develop and validate applications that are less costly, reduce side effects and achieve better clinical results than existing treatments. 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 twenty center clinical trial that we are sponsoring which could validate TTT as an effective therapy for the majority of patients with wet AMD. In November 2001, we announced that enrollment for a study on dry AMD was stopped as sufficient enrollment had been achieved to detect a clinically relevant difference in the clinical outcomes of the study. New applications increase laser usage and may ultimately increase the size of the market for laser photocoagulators.

-2-

Provide Total Disease Management. We intend to expand our product offerings beyond therapeutic laser systems and develop 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

Edgar Filing: IRIDEX CORP - Form 10-K405

acquisitions. By pursuing both therapeutic and diagnostic systems, we intend to provide total disease management solutions to our customers.

Develop New Markets Through Strategic Alliances. We intend to establish strategic alliances in order to expedite and lower the cost of developing and bringing to market new products, both to the ophthalmology and dermatology markets and to markets not currently addressed by our products. Through these alliances, we will seek access to technologies that we do not currently possess. 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. In January 2002, Miravant announced that the top line results of Phase III clinical trials of the photodynamic drug developed (SnET2) did not meet the primary efficacy endpoint in the study. As a result, the future place for SnET2 in the treatment of wet AMD is unclear and we cannot assure you that SnET2 will be timely or successfully pursued through clinical trials by Miravant. See "Management's Discussion and Analysis of Financial Condition and Results of Operations - Factors That May Affect Future Results - We Depend on Collaborative Relationships to Develop, Introduce and Market New Products, Product Enhancements and New Applications."

PRODUCTS

We utilize a systems approach to product design. Each system includes a console, which generates the laser energy, and a number of interchangeable peripheral delivery devices, including disposable delivery devices, for use in specific clinical applications. This approach allows our customers to purchase a basic system and add additional delivery devices as their needs expand or as we develop new applications. We believe that this systems approach also brings economies-of-scale to our product development and manufacturing efforts 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 \$75,000, and consist of laser consoles and peripheral delivery devices.

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. Our dermatology infrared laser light product, the Apex 800, was introduced into the hair removal market in July 2001. Each console weighs 27 pounds, has dimensions of 6"H x 12"W x 17"D, draws 700 Watts of wall power and has a closed loop integrated water cooling system. We believe that the smaller overall sizes, lower weights and low power requirements to operate represent distinct advantages over competing products.

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

Edgar Filing: IRIDEX CORP - Form 10-K405

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 oriented vertically 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. Our DioPexy Probe results in increased precision, less pain and less inflammation than traditional cryotherapy.

Dermatology Delivery Devices:

DioLite Handpiece. The DioLite Handpiece is a hand held instrument that is used 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.

Edgar Filing: IRIDEX CORP - Form 10-K405

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

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

-5-

The following chart lists the eye diseases that can be treated using our photocoagulator systems, including the delivery devices that we offer to treat these diseases. 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 our dermatology laser systems.

| 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 Ad |
| | Focal Retinal Photocoagulation | Visible | Slit Lamp Adapter |
| Proliferative | Pan-Retinal Photocoagulation | Infrared & Visible | Slit Lamp Adapter, Operating Microscope Ad Laser Indirect Ophthalm 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 Ophthalm Operating Microscope Ad EndoProbe |
| | Transscleral Retinal Photocoagulation | Infrared | DioPexy Probe |

Edgar Filing: IRIDEX CORP - Form 10-K405

| | | | |
|----------------------------|-------------------------------|----------|--|
| Retinopathy of Prematurity | Retinal Photocoagulation | Infrared | Laser Indirect Ophthalmoscope |
| Ocular Tumors | Retinal Photocoagulation | Infrared | Slit Lamp Adapter, Operating Microscope Ad Laser Indirect Ophthalm |
| Dermatology Treatments: | | | |
| Vascular Lesions | Selective Photothermolysis | Visible | DioLite Handpiece |
| Pigmented Lesions | Selective Photothermolysis | Visible | DioLite Handpiece |
| Hair Removal | Selective Photothermolysis | Infrared | ColdTip Handpieces, Varispot Handpiece |

(1) This application 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 is supplemented by consultants with specialized expertise. Research

-6-

and development efforts are directed toward both development of new products and development of new applications using existing products, as well as the identification of markets not currently addressed by our products. Our expenditures for research and development totaled approximately \$4,808,000, \$5,265,000 and \$3,925,000 in 2001, 2000 and 1999, 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:

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 multi-center clinical trial which is testing a prophylactic treatment of age-related macular degeneration (PTAMD trial). In November 2001, we announced that enrollment for the PTAMD trial was stopped as sufficient enrollment had been achieved to detect a clinically relevant difference in the clinical outcomes of the study. This trial treats patients with dry AMD using our OcuLight infrared laser systems with the objective of determining whether patient vision is better as a result of treatment compared to no treatment; and secondarily, to determine

Edgar Filing: IRIDEX CORP - Form 10-K405

whether treatment reduces the rate of progression of the disease from the dry form of AMD to the wet form of AMD.

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 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 have been collaborating with Miravant in commercializing this PDT approach to treat "classic" wet AMD. The Phase III clinical trial was fully enrolled in December 1999. In January of 2002, Miravant announced that the top line results of the trial indicated that SnET2, the photodynamic drug developed, did not meet the primary efficacy endpoint in the study population. The future place for SnET2 in the treatment of wet AMD is unclear. We cannot assure you that SnET2 will be timely or successfully pursued through clinical trials by Miravant. 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 sponsoring, is currently enrolling patients. The Data Safety Monitoring Committee (DSMC) for the TTT clinical trial meets semiannually to evaluate the status of the study. 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. Preliminary results reported by both centers have been favorable.

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

-7-

Diabetic Retinopathy. Studies are underway to investigate the treatment of diabetic retinopathy using the MicroPulse (minimal impact sub-visible threshold) infrared photocoagulation available in our OcuLight SLx product 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 the TTT approach.

CUSTOMERS AND CUSTOMER SUPPORT

Our products are currently sold to ophthalmologists, including glaucoma specialists, retinal specialists, pediatric ophthalmologists, dermatologists and plastic surgeons. Other customers include research and teaching hospitals, government installations, surgi-centers and hospitals. No customer or distributor accounted for 10% or more of total sales in 2001, 2000 or 1999. See "Management's Discussion and Analysis of Financial Condition and our Results of Operations."

We are continuing our efforts to broaden our customer base through the development of new products and new applications including new diagnostic products for use by ophthalmologists and dermatologists. We currently estimate that there are approximately 20,000 ophthalmologists in the United States and 50,000 internationally who are each potential customers. We believe there are approximately 10,000 dermatologists and approximately 9,000 plastic surgeons in the U.S. who are potential customers. Additionally, we estimate that there are

Edgar Filing: IRIDEX CORP - Form 10-K405

approximately 4,900 and 18,000 hospitals in the United States and internationally, respectively, as well as approximately 2,300 ambulatory surgical centers in the United States which potentially represent multiple unit sales. Because independent ophthalmologists and dermatologists frequently practice at their own offices as well as through affiliation with hospitals or other medical centers, each independent ophthalmologist, dermatologist, plastic surgeon, hospital and medical center is a potential customer for our products.

We seek to provide superior customer support and service. We maintain an "around-the-clock" telephone service line to service our customers. If a problem with a product cannot be diagnosed and resolved by telephone, a replacement unit is shipped overnight to any domestic customer and by the most rapid delivery means available to any international customer, and the problem unit is returned to us. The small size and rugged design of our products allows for economical shipment and quick response to customers almost anywhere in the world.

SALES AND MARKETING

We market our products in the United States predominantly through our direct sales force. As of December 29, 2001, we had a total of 12 employees engaged in direct sales efforts within the United States. Our sales and marketing organization is based at our corporate headquarters in Mountain View, California with area sales managers located throughout the United States.

To support our sales process, we conduct marketing programs which include direct mail, trade shows, public relations, and advertising in trade and academic journals and newsletters. We annually participate in approximately 87 trade shows or meetings in the United States and approximately 65 trade shows or meetings internationally. These meetings allow us to present our products to existing and prospective buyers.

International product sales represented 41.3%, 35.6% and 38.9% of our sales in 2001, 2000 and 1999, respectively. Our international sales are made principally to customers in Europe and the Asia/Pacific Rim region. Our products are sold internationally through our 67 independent distributors into 91 countries. International sales are administered through our corporate headquarters in Mountain View, California, along with four international

-8-

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 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. We believe

Edgar Filing: IRIDEX CORP - Form 10-K405

that 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.

OPERATIONS

The manufacture of our infrared and visible light photocoagulators and the related delivery devices is a highly complex and precise process. Completed systems must pass quality control and reliability tests before shipment. Our products may also suffer from product defects or failures after being shipped to the customer despite testing because of the complex nature of our products.

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

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

-9-

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. See Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations -- Factors That May Affect Future Results--We Are Subject to Government Regulation."

COMPETITION

Competition in the market for devices used for ophthalmic and 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

Edgar Filing: IRIDEX CORP - Form 10-K405

performance, characteristics and functionality, ease of use, scalability, durability and cost. In addition to other companies that manufacture photocoagulators and dermatological devices, we compete with pharmaceutical solutions, other technologies and other surgical techniques available in both the dermatologic and ophthalmic markets. Our principal competitors in ophthalmology are Lumenis Ltd., Nidek, Inc., Carl Zeiss, Inc., Alcon International and Quantel. All of these companies currently offer a competitive, semiconductor-based laser system in ophthalmology. Our principal competitors in dermatology are Lumenis Ltd., Laserscope, Candela Corporation and Altus Medical Inc. Some competitors have substantially greater financial, engineering, product development, manufacturing, marketing and technical resources than we do. Some companies also have greater name recognition than us and long-standing customer relationships. In addition, other medical companies, academic and research institutions, or others, may develop new technologies or therapies, including medical devices, surgical procedures or pharmacological treatments 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 twelve United States patents and one foreign patent on the technologies related to our products and processes. We have approximately eight pending patent applications in the United States and six foreign pending patent applications that have been filed. 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 addition to patents, we rely on trade secrets and proprietary know-how which we seek to protect, in part, through proprietary information agreements with employees, consultants and other parties. Our proprietary information agreements with our employees and consultants contain provisions

-10-

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

Edgar Filing: IRIDEX CORP - Form 10-K405

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 of America until patents are issued and are maintained in secrecy for a period of time outside the United States of America, 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.

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, the terms of any license may not be reasonable and may result in substantial costs to us, including 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. See "Management's Discussion and Analysis of Financial Condition and Results of Operations--Factors That May Affect Future Results--We Rely on Patents and Proprietary Rights."

GOVERNMENT REGULATION

The medical devices to be marketed and manufactured by us are subject to extensive regulation by numerous governmental authorities, including federal, state, and foreign governmental agencies. Pursuant to the Federal Food, Drug, and Cosmetic Act, as amended, and the regulations promulgated thereunder (the "FDA Act"), the 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 Class III device can be introduced into the market, the manufacturer must generally obtain marketing clearance through either a 510(k)

Edgar Filing: IRIDEX CORP - Form 10-K405

premarket notification or a PMA. A 510(k) clearance will be granted if the submitted information establishes that the proposed device is "substantially equivalent" to a legally marketed Class I or II medical device, or to a Class III medical device for which the FDA has not called for a PMA. The FDA may determine that a proposed device is not substantially equivalent to a legally marketed device, or that additional information or data are needed before a substantial equivalence determination can be made. A request for additional data may require that clinical studies of the device's safety and efficacy be performed.

Commercial distribution of a device for which a 510(k) notification is required can begin only after the FDA issues an order finding the device to be "substantially equivalent" to a previously approved 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.

A "not substantially equivalent" determination, or a request for additional information, could delay the market introduction of new products that fall into this category and could have a materially adverse effect on our business, financial condition and results of operations. For any of our products that are cleared through the 510(k) process, such as our Apex 800 system, modifications or enhancements that could significantly affect the safety or efficacy of the device or that constitute a major change to the intended use of the device will require new 510(k) submissions.

A PMA application must be 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

Edgar Filing: IRIDEX CORP - Form 10-K405

issue a PMA approval letter, authorizing commercial marketing of the device for certain indications. The FDA may also determine that additional

-12-

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.

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

Edgar Filing: IRIDEX CORP - Form 10-K405

("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

-13-

country to country. Many countries also impose product standards, packaging, requirements, labeling requirements and import restrictions on devices. In addition, each country has its own tariff regulations, duties and tax requirements. The approval by the FDA and foreign government authorities is unpredictable and uncertain. The necessary approvals or clearances may not be granted on a timely basis, if at all. Delays in receipt of, or a failure to receive, such approvals or clearances, or the loss of any previously received approvals or clearances, could have a material adverse effect on our business, financial condition and results of operations.

Changes in existing requirements or adoption of new requirements or policies by the FDA or other foreign and domestic regulatory authorities could adversely affect our ability to comply with regulatory requirements. Failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition and results of operations. We may be required to incur significant costs to comply with laws and regulations in the future. These laws or regulations may have a material adverse effect upon our business, financial condition or results of operations.

REIMBURSEMENT

The cost of a significant portion of medical care in the United States is funded by government programs, health maintenance organizations and private insurance plans. Our products are typically purchased by doctors, clinics, hospitals and other users, which bill various third-party payers, such as government programs and private insurance plans, for the health care services provided to their patients. Government imposed limits on reimbursement of hospitals and other health care providers have significantly impacted the spending budgets of doctors, clinics and hospitals to acquire new equipment, including our products. Under certain government insurance programs, a health care provider is reimbursed for a fixed sum for services rendered in treating a patient, regardless of the actual charge for such treatment. The Center for Medicare and Medicaid Services (CMS) reimburses hospitals on a prospectively-determined fixed amount for the costs associated with an in-patient hospitalization based on the patient's discharge diagnosis. CMS reimburses physicians a prospectively-determined fixed amount based on the procedure performed, regardless of the actual costs incurred by the hospital or physician in furnishing the care and regardless of the specific devices used in that procedure. Reimbursement issues have affected sales of our ophthalmic products to a greater extent than sales of our dermatologic products since dermatology procedures, in general, are not covered procedures under most insurance programs and the cost of these procedures are paid for by the patient.

Private third-party reimbursement plans are also developing increasingly sophisticated methods of controlling health-care costs through limitation on reimbursable procedures and the exploration of more cost-effective methods of delivering health care. In general, these government and private measures have

Edgar Filing: IRIDEX CORP - Form 10-K405

caused health care providers, including our customers, to be more selective in the purchase of medical products. In addition, changes in government regulation or in private third-party payers' policies may limit or eliminate reimbursement for procedures employing our products, which could have a material adverse effect on our business, results of operations and financial condition. See "Management's Discussion and Analysis of Financial Condition and Results of Operations - Factors That May Affect Future Results - We Depend on Third Party Coverage and Reimbursement Policies."

Doctors, clinics, hospitals and other users of our products may not obtain adequate reimbursement for use of our products from third-party payors. While we believe that the laser procedures using our products have generally been reimbursed, payers may deny coverage and reimbursement for our products if they determine that the device was not reasonable and necessary for the purpose used, was investigational or was not cost-effective. For example, during July 2000, the CMS advised that claims for reimbursement for certain AMD procedures that use our OcuLight SLx laser system would not be reimbursed by CMS. As a result, since July 2000, sales of the OcuLight SLx laser system have dropped significantly. In September 2000, CMS changed its position and advised that claims for reimbursement for two of the AMD procedures can be submitted for reimbursement with coverage and payment to be determined by the local medical carriers in their discretion. Sales of the OcuLight SLx continue, albeit at a lower level, because the OcuLight SLx can also be used for other retinal procedures that are reimbursable by the CMS. Furthermore, since CMS advisories are for domestic third party CMS payers, they are not likely to affect international sales. We believe domestic sales of the OcuLight SLx laser system will continue at these lower levels until more medical carriers reimburse for performing such AMD procedures or until CMS advises that claims for these procedures may be submitted directly to CMS at the national level. Two carriers, Noridian Mutual Insurance, which is the CMS Part B carrier for Alaska, Arizona, Colorado, Hawaii, Iowa, Nevada, North Dakota, Oregon, South Dakota, Washington and Wyoming, as well as Cigna, which is the carrier for North Carolina, Tennessee and Idaho, have made written coverage decisions approving the use of the TTT protocol, using our OcuLight SLx laser system for the treatment of wet AMD. We believe that more medical carriers will reimburse for these procedures and CMS will allow direct reimbursement for them when they are further validated by clinical studies. We are sponsoring a

-14-

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."

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. 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.

Edgar Filing: IRIDEX CORP - Form 10-K405

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 29, 2001, we had a total of 125 full-time employees, including 52 in operations, 34 in sales and marketing, 26 in research and development and 13 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 29, 2001, we employed 3 such persons. We intend to hire additional personnel during the next twelve months primarily in the direct sales and production areas. Our future success will depend in part on our ability to attract, train, retain and motivate highly qualified employees, who are in great demand. We may not be successful in attracting and retaining such personnel. Our employees are not represented by a collective bargaining organization, and we have never experienced a work stoppage or strike. We consider our employee relations to be good.

EXECUTIVE OFFICERS OF THE COMPANY

Our executive officers and their ages as of December 29, 2001 were as follows:

-15-

| Name ---- | Age --- | Position ----- |
|-----------------------|------------|---|
| Theodore A. Boutacoff | 54 | President, Chief Executive Officer and Director |
| Robert Kamenski | 47 | Chief Financial Officer and Vice President, Administration |
| Eduardo Arias | 57 | Senior Vice President, International Sales and Business Development |
| Timothy Powers | 40 | Vice President, Operations |
| James L. Donovan | 64 | 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, from April 1989 to September 1991, Mr. Arias served as IRIDEX Vice President, Sales & Marketing and since September 1991 served as Senior Vice President, Worldwide Sales. Prior to co-founding the Company, Mr. Arias held various positions, including Director of Marketing and

Edgar Filing: IRIDEX CORP - Form 10-K405

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. He has served as a member of our Board of Directors since February 1989. From February 1989 to October 1997, Mr. Donovan served as our Chief Financial Officer, except during the period June to November 1996. He currently serves 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.

-16-

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, which expired in 2002, was renewed for two years through 2004.

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.

-17-

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 2002 | | |
| First Quarter (through March 20, 2002) | \$ 6.047 | \$ 4.170 |

Edgar Filing: IRIDEX CORP - Form 10-K405

FISCAL 2001

| | | |
|----------------------|----------|----------|
| First Quarter | \$ 6.313 | \$ 4.125 |
| Second Quarter | 4.400 | 3.000 |
| Third Quarter | 4.250 | 3.250 |
| Fourth Quarter | 5.446 | 3.850 |

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 2002

On March 20, 2002, the closing price on the NASDAQ National Market for our Common Stock was \$4.438 per share. As of March 20, 2002, 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.

-18-

ITEM 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data as of December 29, 2001 and December 30, 2000, and for the years ended December 29, 2001, December 30, 2000 and January 1, 2000, has been derived from, and are qualified by reference to, our audited consolidated financial statements included herein. The selected consolidated statement of operations data for the years ended January 2, 1999 and December 31, 1997 and the consolidated balance sheet data as of January 1, 2000, January 2, 1999 and December 31, 1997 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."

| | Fiscal Year 2001 ----- | Fiscal Year 2000 ----- | Fisc Yea 199 ----- |
|---|---------------------------------|---------------------------------|-----------------------------|
| CONSOLIDATED STATEMENT OF OPERATIONS DATA: | | | |
| Sales | \$ 27,275 | \$ 32,838 | \$ 26, |
| Cost of sales | 14,205 | 14,506 | 11, |
| Gross profit | 13,070 | 18,332 | 14, |

Edgar Filing: IRIDEX CORP - Form 10-K405

| | | | |
|---|------------|----------|-------|
| Operating expenses: | | | |
| Research and development | 4,808 | 5,265 | 3, |
| Selling, general and administrative | 10,251 | 10,747 | 9, |
| | ----- | ----- | ----- |
| Total operating expenses | 15,059 | 16,012 | 13, |
| | ----- | ----- | ----- |
| Income (loss) from operations | (1,989) | 2,320 | 1, |
| Interest and other income..... | 426 | 569 | |
| | ----- | ----- | ----- |
| Income (loss) before provision for income taxes | (1,563) | 2,889 | 2, |
| Benefit from (provision) for income taxes | 962 | (809) | (|
| | ----- | ----- | ----- |
| Income (loss) from continuing operations | (601) | 2,080 | 1, |
| Income (loss) from operations of discontinued Laser Research segment (net of applicable income tax benefit (provision) of \$124, \$(131), \$(80), \$213 and \$(283) respectively) | (204) | 336 | |
| Income (loss) on disposal of Laser Research segment (net of applicable income tax benefit (provision) of \$315, \$0, \$0, \$0 and \$0 respectively) | (468) | -- | |
| | ----- | ----- | ----- |
| Net income (loss) | \$ (1,273) | \$ 2,416 | \$ 1, |
| | ===== | ===== | ===== |

-19-

| | | | |
|---|-----------|---------|-------|
| Basic net income (loss) per share: | | | |
| Continuing Operations | \$ (0.09) | \$ 0.31 | \$ 0 |
| Discontinued Operations | (0.10) | 0.05 | 0 |
| | ----- | ----- | ----- |
| Basic net income (loss) per common share | \$ (0.19) | \$ 0.36 | \$ 0 |
| | ===== | ===== | ===== |
| Diluted net income (loss) per share: | | | |
| Continuing Operations | \$ (0.09) | \$ 0.29 | \$ 0 |
| Discontinued Operations | (0.10) | 0.04 | 0 |
| | ----- | ----- | ----- |
| Diluted net income (loss) per share | \$ (0.19) | \$ 0.33 | \$ 0 |
| | ===== | ===== | ===== |
| Shares used in net income (loss) per common share basic calculations | | | |
| | 6,757 | 6,637 | 6, |
| | ===== | ===== | ===== |
| Shares used in net income (loss) per common share diluted calculations | | | |
| | 6,757 | 7,285 | 6, |
| | ===== | ===== | ===== |

| | December 29, 2001 | December 30, 2000 | January 1, 2000 |
|----------------------------------|----------------------|----------------------|--------------------|
| | ----- | ----- | ----- |
| CONSOLIDATED BALANCE SHEET DATA: | | | |
| Cash, cash equivalents and | \$ 9,102 | \$12,994 | \$13,148 |
| available-for-sale securities | | | |
| Working capital | 26,374 | 27,005 | 23,842 |
| Total assets | 33,788 | 35,025 | 32,763 |
| Total stockholders' equity | 29,833 | 30,500 | 27,504 |

-20-

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

OVERVIEW

IRIDEX Corporation is the leading worldwide provider of semiconductor-based laser systems used to treat eye diseases in ophthalmology and skin afflictions in dermatology. Our products are sold in the United States predominantly through a direct sales force and internationally through 67 independent distributors into 91 countries.

Our revenues arise primarily from the sale of our IRIS Medical OcuLight Systems, IRIDERM DioLite 532 and Apex 800 systems, delivery devices, disposables and, to a lesser extent, revenues from service and support activities. Our current family of OcuLight systems includes the IRIS Medical OcuLight SL, OcuLight SLx, OcuLight GL and OcuLight GLx Laser Photocoagulation systems. 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. We believe that future growth in unit sales will be derived from growth in the market for photocoagulator products, replacement of installed photocoagulators which use vacuum tube-based technology and from the adoption of new procedures.

Sales to international distributors are made on open credit terms or letters of credit. Sales of our products internationally currently are denominated in United States dollars and, accordingly, are subject to risks associated with international monetary conditions and currency fluctuations. In general, strengthening of the U.S. dollar relative to a foreign currency increases the cost of our product to our customers. Other risks that international sales are subject to include shipping delays, generally longer receivable collection periods, changes in applicable regulatory policies, domestic and foreign tax policies, trade restrictions, duties and tariffs and economic and political instability. Future currency fluctuations or other factor 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."

-21-

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:

Edgar Filing: IRIDEX CORP - Form 10-K405

| | Fiscal Year Ended 2001 | Fiscal Year Ended 2000 | Fiscal Year Ended 1999 |
|---|---------------------------|---------------------------|---------------------------|
| Sales | 100.0% | 100.0% | 100.0% |
| Cost of sales | 52.1 | 44.2 | 44.2 |
| Gross profit | 47.9 | 55.8 | 55.8 |
| Operating expenses: | | | |
| Research and development | 17.6 | 16.0 | 14.9 |
| Sales, general and administrative | 37.6 | 32.7 | 35.0 |
| Total operating expenses | 55.2 | 48.7 | 49.9 |
| Operating income (loss) from continuing operations | (7.3) | 7.1 | 5.9 |
| Other income, net | 1.6 | 1.7 | 2.1 |
| Income (loss) from continuing operations before provision for income taxes | (5.7) | 8.8 | 8.0 |
| Benefit (provision) for income taxes | 3.5 | (2.5) | (2.6) |
| Income (loss) from continuing operations | (2.2) | 6.3 | 5.4 |
| Income (loss) from discontinued operations (net of tax) | (2.5) | 1.0 | 0.6 |
| Net income (loss) | (4.7)% | 7.3% | 6.0% |

-22-

The following table sets forth for the periods indicated the amount of sales for our operating segments and sales as a percentage of total sales.

| | Year Ending December 29, 2001 | | Year Ending December 30, 2000 | | Year Ending January 1, 2000 | |
|----------------|----------------------------------|---------------------------------|----------------------------------|---------------------------------|--------------------------------|---------------------------------|
| | Amount | Percentage of total sales | Amount | Percentage of total sales | Amount | Percentage of total sales |
| Domestic | \$16,004 | 58.7% | \$21,133 | 64.4% | \$16,134 | 61.1% |
| International | 11,271 | 41.3% | 11,705 | 35.6% | 10,257 | 38.9% |
| Total | \$27,275 | 100.0% | \$32,838 | 100.0% | \$26,391 | 100.0% |
| Ophthalmology: | | | | | | |
| Domestic | \$10,976 | 40.2% | \$16,559 | 50.4% | \$11,088 | 42.0% |
| International | 9,946 | 36.5% | 10,506 | 32.0% | 8,109 | 30.7% |
| Total | \$20,922 | 76.7% | \$27,065 | 82.4% | \$19,197 | 72.7% |
| Aesthetics: | | | | | | |
| Domestic | \$ 5,028 | 18.4% | \$ 4,574 | 13.9% | \$ 5,046 | 19.1% |
| International | 1,325 | 4.9% | 1,199 | 3.6% | 2,148 | 8.1% |

Edgar Filing: IRIDEX CORP - Form 10-K405

| | | | | | | |
|-------|----------|-------|----------|-------|----------|-------|
| Total | \$ 6,353 | 23.3% | \$ 5,773 | 17.5% | \$ 7,194 | 27.2% |
|-------|----------|-------|----------|-------|----------|-------|

Combined Ophthalmology and Dermatology Sales

In 2001, sales decreased by 16.9% to \$27.3 million from \$32.8 million in 2000, primarily as a result of decreased unit sales for our ophthalmology products. Domestic sales, which represented 58.7% of total sales, decreased by \$5.1 million or 24.3% primarily as a result of weakened economic conditions in the United States of America. We expect future growth in domestic sales to be primarily derived from sales of the OcuLight SLx and the Apex 800 hair removal laser for dermatology. International sales, which were 41.3% of total sales, decreased by \$0.4 million or 3.7% primarily as a result of the strength of the U.S. dollar, which resulted in higher prices for our products in foreign markets. We expect future growth in international sales to be primarily derived from sales of the Apex 800 hair removal laser for dermatology. We face challenges marketing and selling our products in the current difficult economic environment, both domestically and internationally, and expect to continue to face these challenges for the foreseeable future. See "-- Factors That May Affect Future Results -- Our Business has been Adversely Impacted by the Current Worldwide Economic Slowdown and Related Uncertainties."

In 2000, sales increased by 24.4% to \$32.8 million from \$26.4 million in 1999. The increase in our sales in 2000 was primarily due to increased unit sales for our ophthalmology products, offset in part by overall decreases in average selling prices. Domestic sales increased by \$5.0 million or 31.0% to 64.4% of total net sales. International sales increased in absolute dollars by 14.1% to \$11.7 million, however as a percentage of total sales, international sales decreased to 35.6% in 2000.

Ophthalmology Sales

Ophthalmology sales decreased in 2001 by \$6.1 million or 22.7% to \$20.9 million. Domestic ophthalmology sales decreased by \$5.6 million or 33.7% to \$11.0 million. International ophthalmology sales decreased by \$0.6 million or 5.3% to \$9.9 million. The decrease in domestic sales was due primarily to weakened economic conditions in the U.S. In addition, sales of our OcuLight SLx, in particular, were impacted in the

-23-

United States as a result of uncertainties surrounding reimbursement by the Center for Medicare and Medicaid (CMS) for certain procedures to treat age-related macular degeneration (AMD) using our products.

In 2000, ophthalmology sales increased \$7.9 million or 41.0% to \$27.1 million. Domestic ophthalmology sales increased \$5.5 million or 49.3% to \$16.6 million. International ophthalmology sales increased \$2.4 million or 29.6% to \$10.5 million. The overall increase in ophthalmology sales in 2000 related primarily to increased unit sales of the OcuLight SLx to treat AMD and to sales of the OcuLight 664 offset in part by decreased average selling prices. The OcuLight 664 is a product co-developed with Miravant. See further discussion under "Factors That May Affect Future Results--We Depend on Collaborative Relationships to Develop, Introduce and Market New Products, Product Enhancements and New Applications."

Dermatology Sales

Dermatology sales increased in 2001 by \$0.6 million or 10.0% to \$6.4

Edgar Filing: IRIDEX CORP - Form 10-K405

million. Domestic dermatology sales increased by \$0.5 million or 9.9% to \$5.0 million. International dermatology sales increased by \$0.1 million or 10.5% to \$1.3 million. The overall increases in dermatology sales were primarily related to sales of our Apex 800 hair removal laser system, which we introduced in July 2001. We expect that current economic slowdown may adversely affect sales of our dermatology products, particularly the Apex 800 laser system, to a greater extent than sales of ophthalmic products since aesthetic procedures are typically elective and therefore can be deferred, while ophthalmology procedures are typically not deferred.

Dermatology sales decreased in 2000 by \$1.4 million or 19.8% to \$5.8 million. Domestic aesthetics sales decreased by \$0.5 million or 9.4% to \$4.6 million. International dermatology sales decreased \$1.0 million or 44.2% to \$1.2 million. The overall decrease in dermatology sales in 2000 was due primarily to concentration of our sales and marketing efforts on the introduction of our Apex 800 hair removal system, the first unit of which was not sold until the following year and which impacted sales efforts for our existing DioLite 532 product.

Gross Profit. Gross profit was \$13.1 million in 2001, \$18.3 million in 2000 and \$14.7 million in 1999. Gross profit represented 47.9% of sales in 2001, 55.8% in 2000 and 55.8% in 1999. Gross profit as a percentage of sales decreased in 2001 as compared to 2000 due primarily to the decreased sales volume of the OcuLight SLx, which has a relatively higher gross margin. In addition, fixed manufacturing costs were spread over a lower sales volume and we experienced higher initial production costs of our Apex 800 hair removal laser. We also charged to expense \$0.3 million of inventory related to the OcuLight 664 (see further discussion under "Factors That May Affect Future Results -- We Depend on Collaborative Relationships to Develop, Introduce and Market New Products, Product Enhancements and New Applications.").

Gross profit as a percentage of sales did not change in 2000 as compared to 1999 due primarily to increased sales of OcuLight SLx systems, a high gross margin product, offset by decreased sales of the DioLight 532 and lower average selling prices for the DioLight 532. In general, 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. See "Factors That May Affect Future Results--Our Operating Results May Fluctuate From Quarter to Quarter."

Research and Development. Research and development expenses decreased by 8.7% in 2001 to \$4.8 million and increased by 34.1% in 2000 to \$5.3 million. These expenses were 17.6% of sales in 2001, 16.0% of sales in 2000 and 14.9% of sales in 1999. The decrease in 2001, in absolute dollars, was primarily due to completion of the Apex 800 and cost containment measures. The increase in research and development expenses in 2001, as a percentage of sales, was driven by the decrease in sales which exceeded the decrease in research and development expense. The increase in 2000, in absolute dollars and as a percentage of sales, was primarily due to personnel and prototype expenses, related to the development of the Apex 800 hair removal dermatology system, development costs associated with unreleased ophthalmology products as well as increased clinical study costs. We expect these expenses for research and development to increase in absolute dollars during 2002 in connection with new product development activities and clinical studies.

Sales, General and Administrative. Sales, general and administrative expenses decreased by 4.6% in 2001 to \$10.3 million and increased by 16.5% in 2000 to \$10.7 million from \$9.2 million in 1999. These expenses were 37.6% of sales in 2001, 32.7% of sales in 2000 and 35.0% of sales in 1999. The decrease in sales, general and administrative expenses, in absolute dollars, from 2000 to 2001 was primarily due to lower commissions, fewer sales personnel and other cost containment actions. The increase, as a percentage of net sales, from 2000 to 2001 was due to the fact that the decrease in the level of sales exceeded the decrease in sales, general and administrative expense. From 1999 to 2000, sales, general and administrative expenses, in absolute dollars, increased due to hiring of additional sales and marketing employees as well as expanded marketing programs 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 was necessary to support our expanded operations. The decrease in sales, general and administrative expense, as a percentage of net sales, from 1999 to 2000 was due to the greater increase in revenue relative to the increase in sales, general and administrative expense.

Other income, net. Other income, net consists primarily of interest income. Interest income was \$378,000, \$552,000 and \$469,000 in 2001, 2000 and 1999, respectively. This income was primarily from interest earned on available-for-sale securities. Interest income decreased in 2001 compared with 2000 because of lower interest rates and overall lower average cash balances during the year.

Income Taxes. In 2001, the Company's effective rate was a benefit of 62% primarily as a result of the level of tax credits for research and development activities relative to the loss for 2001. We had an effective tax rate of 28% and 32% in 2000 and 1999, respectively. The tax rate for 2001, 2000 and 1999 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.

Discontinued Operations. In April 2001, we discontinued our Laser Research segment. In the first quarter of 2001, we recorded a loss of \$893,000 (net of a \$542,000 tax benefit). In the fourth quarter of 2001, we adjusted the loss on discontinued operations to \$672,000 (net of a \$439,000 tax benefit). Revenues for this segment were \$599,000 for 2000 and \$460,000 for 1999. Costs and operating expenses of the Laser Research segment were \$132,000 for 2000 and \$209,000 for 1999. Sales, general and administrative costs and indirect costs of manufacturing historically were not allocated to the Laser Research segment.

LIQUIDITY AND CAPITAL RESOURCES

At December 29, 2001, our primary sources of liquidity included cash and cash equivalents of \$4.6 million and available-for-sale securities of \$4.5 million, for a total of \$9.1 million. In addition, we have available \$4.0 million under our unsecured line of credit which bears interest at the bank's prime rate and expires in October 2002. As of December 29, 2001, no borrowings were outstanding under this credit facility. We expect to renew the line of credit in October 2002 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 2002.

We used \$5,385,000 in cash and cash equivalents during 2001. In 2000, we

Edgar Filing: IRIDEX CORP - Form 10-K405

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

-25-

Net cash used in operations totaled \$3,635,000 in 2001 as compared with \$74,000 used in operations in 2000 and \$2,862,000 generated from operations in 1999. In 2001, uses of cash included increases in net inventories of \$2,841,000, a net loss of \$1,273,000, increases in deferred income taxes of \$332,000, decreases in accrued expenses of \$338,000, decreases in accounts payable of \$232,000 and decreases in net accounts receivable of \$56,000 offset by sources of cash from operations which included depreciation of \$859,000, tax benefit of employee stock option plans of \$372,000 and decreases in prepaids and other current assets of \$206,000. In 2000, sources of cash from operations included net income of \$2,416,000, depreciation of \$893,000, increases in accounts payable of \$280,000 and decreases in net accounts receivable of \$250,000, partially offset by uses of cash from operations with increases in net inventories of \$2,465,000 and decreases in accrued expenses of \$1,014,000. In 1999, sources of cash included net income of \$1.6 million, depreciation of \$721,000, increases in accrued expenses of \$2.4 million and increases in accounts payable of \$249,000, partially offset by uses of cash with increases of deferred income taxes of \$846,000, increases in net inventories of \$752,000 and increases in accounts receivable of \$623,000.

We used \$1,991,000 for investing activities in 2001. In 2000, we used \$133,000 and in 1999 we generated \$982,000 from investing activities. The generation or use of cash was primarily due to the sale or purchase and proceeds of available-for-sale securities and the acquisition of fixed assets.

Net cash provided by financing activities during 2001, 2000 and 1999 was \$241,000, \$560,000 and \$10,000, respectively, which consisted primarily of issuance of stock, in connection with our employee stock programs, offset in part by purchase of treasury stock of \$115,000 in 2001 and \$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. In 2001, we purchased 27,000 shares of our Common Stock from the open market.

CRITICAL ACCOUNTING POLICIES

Revenue Recognition

Revenue from product sales is recognized upon receipt of a purchase order and product shipment provided no significant obligations remain and collection of the receivables is deemed probable. Up-front fees received in connection with product sales are deferred and recognized over the associated product shipments. We accrue 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. Our warranty policy is effective for shipped products which are considered defective or fail to meet the product specifications.

Sales Returns Allowance and Allowance for Doubtful Accounts

In the process of preparing financial statements we must make estimates and assumptions that affect the reported amount of assets and disclosures of contingent assets and liabilities at the date of the financial statements and

Edgar Filing: IRIDEX CORP - Form 10-K405

the reported amounts of revenues and expenses during the reported period. Specifically, we must estimate future product returns related to current period product revenue. We analyze historical returns, current economic trends and changes in customer demand and acceptance of our products when evaluating the adequacy of the sales returns allowance and other allowances. Significant management judgements and

-26-

estimates must be made and used in connection with establishing the sales returns and other allowances in any accounting period. Material differences may result in the amount and timing of our revenue for any period if management made different judgements or utilized different estimates. The provision for sales returns amounted to \$0.2 million in 2001. Similarly our management must make estimates of the uncollectibility of our accounts receivable. Management specifically analyzes accounts receivable and analyzes historical bad debts, customer concentrations, customer credit-worthiness, current economic trends and changes in our customer payment terms when evaluating the adequacy of the allowance for doubtful accounts. Our accounts receivable balance was \$8.1 million, net of allowance for doubtful accounts of \$0.3 million as of December 29, 2001.

Inventories

Inventories are stated at the lower of cost or market. Cost is determined on a standard cost basis which approximates actual cost on a first-in, first-out (FIFO) method. Lower of cost or market is evaluated by considering obsolescence, excessive levels of inventory, deterioration and other factors.

Income Taxes

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.

CONTRACTUAL OBLIGATIONS

The following table summarizes contractual obligations (in thousands):

| Contractual Obligations | Payments Due by Period | | |
|-------------------------------------|------------------------|---------------------|----------------|
| | Total | Less than 1 Year | 1 - 3 Years |
| Operating Leases | \$1,452 | \$ 650 | \$ 802 |
| Unconditional Purchase Obligations* | \$2,985 | \$2,598 | \$ 387 |
| Total Contractual Cash Obligations | \$4,437 | \$3,248 | \$1,189 |

Edgar Filing: IRIDEX CORP - Form 10-K405

* Contractual Purchase Obligations have varying cancellation terms

-27-

COMMERCIAL COMMITMENTS

We have available \$4.0 million under our unsecured line of credit which bears interest at the bank's prime rate and expires in October 2002. As of December 29, 2001, no borrowings were outstanding under this credit facility.

RECENT ACCOUNTING PRONOUNCEMENTS

In July 2001, the Financial Accounting Standards Board issued SFAS No. 141 "Business Combinations," which establishes financial accounting and reporting for business combinations and supersedes APB Opinion No. 16, Business Combinations, and FASB Statement No. 38, Accounting for Preacquisition Contingencies of Purchased Enterprises. It requires that all business combinations in the scope of this Statement are to be accounted for using one method, the purchase method. The provisions of this Statement apply to all business combinations initiated after June 30, 2001, and also applies to all business combinations accounted for using the purchase method for which the date of acquisition is July 1, 2001, or later. We believe that adoption of the standard will not have a material effect on our financial position or results of operations.

In July 2001, the Financial Accounting Standards Board issued SFAS No. 142 "Goodwill and Other Intangible Assets," which establishes financial accounting and reporting for acquired goodwill and other intangible assets and supersedes APB Opinion No. 17, Intangible Assets. It addresses how intangible assets that are acquired individually or with a group of other assets (but not those acquired in a business combination) should be accounted for in financial statements upon their acquisition, after they have been initially recognized in the financial statements. The provisions of this Statement are effective starting with fiscal years beginning after December 15, 2001. We believe that SFAS No. 142 will not have a material effect on our financial position or results of operation.

In October 2001, the Financial Accounting Standards Board issued SFAS 144 "Accounting for the Impairment or Disposal of Long-Lived Assets" that develops one accounting model for long lived assets that are to be disposed of by sales and requires long-lived assets that are to be disposed of by sales be measured at the lower of book value or fair value less cost to sell. Additionally, SFAS No. 144 expands the scope of discontinued operations to include all components of an entity with operations that (1) can be distinguished from the rest of the entity and (2) will be eliminated from the ongoing operations of the entity in a disposal transaction. SFAS No. 144 supercedes SFAS No. 121 "Accounting for the Impairment of Long-Lived Assets to be Disposed Of." SFAS No. 144 applies to all long-lived assets (including discontinued operations) and consequently amends Accounting Principles Board Opinion No. 30 (APB 30), Reporting Results of Operations Reporting the Effects of Disposal of a segment of a business. Management does not expect the adoption of SFAS 144 to have a material impact on our financial position and results of operations.

-28-

FACTORS THAT MAY AFFECT FUTURE RESULTS

WE RELY ON CONTINUED MARKET ACCEPTANCE OF OUR EXISTING PRODUCTS. We currently market visible and infrared light semiconductor-based photocoagulator

Edgar Filing: IRIDEX CORP - Form 10-K405

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

- Product performance, procedures and price;
- 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; and
- The level of reimbursement for treatments administered with our products.

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

WE FACE STRONG COMPETITION IN OUR MARKETS AND EXPECT THE LEVEL OF COMPETITION TO GROW IN THE FORSEEABLE FUTURE. 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 Lumenis Ltd., Nidek, Inc., Carl Zeiss, Inc., Alcon International and Quantel. All of these companies currently offer a competitive, semiconductor-based laser system in ophthalmology. Our principal competitors in dermatology are Lumenis Ltd., Laserscope, Candela Corporation and Altus Medical Inc. Some competitors have substantially greater financial, engineering, product development, manufacturing, marketing and technical resources than we do. Some companies also have greater name recognition than us and long-standing customer relationships. In addition 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.

OUR FUTURE SUCCESS DEPENDS 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. Introduction of new products and new applications will require that we effectively transfer production processes from research and development to manufacturing and effectively coordinate with our suppliers. In addition, we must successfully sell and achieve market acceptance of new products and applications and enhanced versions of existing products. The extent of, and rate at which, market acceptance and penetration are achieved by future products, is a function of many variables. 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

Edgar Filing: IRIDEX CORP - Form 10-K405

enhanced versions of existing products and achieve market acceptance of new products and new applications could have a material adverse effect on our operating results and would cause our net revenues to decline.

WE FACE RISKS OF MANUFACTURING. The manufacture of our infrared and visible light photocoagulators and the related delivery devices is a highly complex and precise process. We assemble critical subassemblies and the final product at our facility in Mountain View, California. Although our OcuLight Systems, DioLite 532 and Apex 800 have been successfully introduced, we continue to face risks associated with manufacturing these products. Various difficulties may occur despite testing. Furthermore, we may experience delays, disruptions, capacity constraints or quality control problems in our manufacturing operations and, as a result, product shipments to our customers could be delayed, which would negatively impact our net revenues.

-29-

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. Some of our suppliers and manufacturers are sole or limited source. In addition, some of these suppliers are relatively small private companies that may discontinue their operations at any time. There are risks associated with the use of independent manufacturers, including 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. For example, we experienced delays in shipping our green laser systems (such as the DioLite 532 for dermatology and the OcuLight GL and GLx for ophthalmology) during the first fiscal quarter of 2001 due to a supply shortage of a key component. We qualified additional sources for this component during the first fiscal quarter of 2001, however, the process of qualifying suppliers is ongoing and may be lengthy, particularly as new products are introduced. 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 impair our ability to offer our existing products, 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 and results of operations would be adversely affected if we are unable to continue to obtain components in the quantity and quality desired and at the prices we have budgeted.

WE DEPEND ON INTERNATIONAL SALES FOR A SIGNIFICANT PORTION OF OUR OPERATING RESULTS. We derive and expect to continue to derive a large portion of our revenue from international sales. In 2001, 2000 and 1999, our international sales were \$11.3 million, \$11.7 million and \$10.3 million, or 41.3%, 35.6%, and 38.9%, respectively, of total sales. We anticipate that international sales will continue to account for a significant portion of our revenues in the foreseeable future. None of our international revenues and costs have been denominated in foreign currencies. As a result, an increase in the value of the U.S. dollar relative to foreign currencies makes our products more expensive and thus less competitive in foreign markets. For example, the current high U.S. dollar relative value to the European currency (the Euro) is making our products less competitive in Europe when compared to European competitors and could negatively

Edgar Filing: IRIDEX CORP - Form 10-K405

impact future sales levels from the region. Our international operations and sales are subject to a number of risks, including:

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

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

WE DEPEND ON 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.

-30-

Third-party payers are increasingly scrutinizing and challenging the coverage of new products and the level of reimbursement for covered products. Doctors, clinics, hospitals and other users of our products may not obtain adequate reimbursement for use of our products from third-party payers. While we believe that the laser procedures using our products have generally been reimbursed, payers may deny coverage and reimbursement for our products if they determine that the device was not reasonable and necessary for the purpose used, was investigational or was not cost-effective. For example, during July 2000, CMS advised that claims for reimbursement for certain AMD procedures, which use our OcuLight SLx laser system would not be reimbursed by CMS. As a result, since July 2000, sales of the OcuLight SLx laser system have dropped significantly. In September 2000, CMS changed its position and advised that claims for reimbursement for two of the AMD procedures can be submitted for reimbursement, with coverage and payment to be determined by the local medical carriers in their discretion. Sales of the OcuLight SLx continue, albeit at a lower level, because the OcuLight SLx can also be used for other retinal procedures with CMS reimbursement. We believe domestic sales of the OcuLight SLx laser system will continue at these lower levels until more medical carriers reimburse for performing such AMD procedures or until CMS advises that claims for these procedures may be submitted directly to CMS at the national level.

Changes in government legislation or regulation or in private third-party payers' 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.

OUR OPERATING RESULTS MAY FLUCTUATE FROM QUARTER TO QUARTER AND YEAR TO YEAR. Our sales and operating results may vary significantly from quarter to

Edgar Filing: IRIDEX CORP - Form 10-K405

quarter and from year to year in the future. Our operating results are affected by a number of factors, many of which are beyond our control. Factors contributing to these fluctuations include the following:

- General economic uncertainties both preceding and following the terrorist attacks on September 11, 2001;
- The timing of the introduction and market acceptance of new products, product enhancements and new applications;
- Changes in demand for our existing line of dermatologic and ophthalmic products;
- The cost and availability of components and subassemblies including the ability of our sole or limited source suppliers to deliver components at the times and prices that we have planned;

-31-

- Fluctuations in our product mix between dermatologic and ophthalmic products and foreign and domestic sales;
- The effect of regulatory approvals and changes in domestic and foreign regulatory requirements;
- Introduction of new products, product enhancements and new applications by our competitors, entry of new competitors into our markets, pricing pressures and other competitive factors;
- Our long and highly variable sales cycle;
- Decreases in the prices at which we can sell our products;
- Changes in customers' or potential customers' budgets, as a result of, among other things, reimbursement policies of government programs and private insurers for treatment that use our products; and
- Increased product development costs.

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

Our expense levels are based, in part, on expected future sales. If sales levels in a particular quarter do not meet expectations, we may be unable to adjust operating expenses quickly enough to compensate for the 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.

OUR BUSINESS HAS BEEN ADVERSELY IMPACTED BY THE WORLDWIDE ECONOMIC SLOWDOWN AND RELATED UNCERTAINTIES. Weaker economic conditions worldwide, particularly in the U.S., have contributed to the current slowdown in our business in general. This has resulted in reduced demand for some of our products, particularly in our dermatology products, such as the Apex 800, increased rate of order cancellations or delays, excess manufacturing capacity

Edgar Filing: IRIDEX CORP - Form 10-K405

under current market conditions and higher overhead costs, as a percentage of revenue. In addition, these economic conditions are making it very difficult for us, our customers and our distributors to forecast and plan future business activities. This level of uncertainty significantly challenges our ability to operate profitably or grow our business. If the economic or market conditions continue or further deteriorate, this may have a material adverse impact on our financial position, results of operations and cash flows.

-32-

WE DEPEND ON COLLABORATIVE RELATIONSHIPS TO DEVELOP, INTRODUCE AND MARKET NEW PRODUCTS, PRODUCT ENHANCEMENTS AND NEW APPLICATIONS. We have entered into collaborative relationships with academic medical centers and physicians in connection with the research and development and clinical testing of our products. We plan to collaborate with third parties to develop and commercialize existing and new products. In May 1996, we executed an agreement with Miravant Medical Technologies, 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. The Phase III clinical trial was fully enrolled in December 1999. In January 2002, Miravant announced that the top line results of the trial indicated that SnET2, the photodynamic drug developed, did not meet the primary efficacy endpoint in the study population. As a result, the future place for SnET2 in the treatment of wet AMD is unclear and we cannot assure you that SnET2 will be timely or successfully pursued through clinical trials by Miravant. In the fourth quarter of 2001, we charged to expense \$0.3 million of inventory related to the OcuLight 664, the laser used by Miravant in the Phase III clinical trials. 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 twelve United States patents and one foreign patent on the technologies related to our products and processes. We have approximately eight pending patent applications in the United States and six foreign pending patent applications that have been filed. 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 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

Edgar Filing: IRIDEX CORP - Form 10-K405

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

-33-

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.

Edgar Filing: IRIDEX CORP - Form 10-K405

In addition, we are also subject to varying product standards, packaging requirements, labeling requirements, tariff regulations, duties and tax requirements. For example, 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. While currently all of our 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 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. We implemented an enterprise-wide management information system in 1998. 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 FACE PRODUCT LIABILITY RISKS THAT MAY ADVERSELY AFFECT OUR BUSINESS OR RESULTS OF OPERATIONS. 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. Although we maintain product liability insurance with coverage limits of \$11.0

-34-

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.

IF WE CANNOT INCREASE OUR SALES VOLUMES, REDUCE OUR COSTS OR INTRODUCE HIGHER MARGIN PRODUCTS TO OFFSET ANY REDUCTIONS IN THE AVERAGE UNIT PRICE OF OUR PRODUCTS, OUR OPERATING RESULTS MAY SUFFER. The average unit price of our products may decrease in the future in response to changes in product mix, competitive pricing pressures, new product introductions by us or our competitors or other factors. If we are unable to offset the anticipated decrease in our average selling prices by increasing our sales volumes, our net revenues will decline. In addition, to maintain our gross margins, we must continue to reduce the manufacturing cost of our products. Further, should average unit prices of our current products decline, we must develop and introduce new products and product enhancements with higher margins. If we cannot maintain our gross margins, our business could be seriously harmed, particularly if the average selling price of our products decreases significantly without a corresponding increase in sales.

IF WE FAIL TO ACCURATELY FORECAST DEMAND FOR OUR PRODUCT AND COMPONENT REQUIREMENTS FOR THE MANUFACTURE OF OUR PRODUCT, WE COULD INCUR ADDITIONAL COSTS OR EXPERIENCE MANUFACTURING DELAYS AND MAY EXPERIENCE LOST SALES OR SIGNIFICANT INVENTORY CARRYING COSTS. We use quarterly and annual forecasts based primarily on our anticipated product orders to plan our manufacturing efforts and

Edgar Filing: IRIDEX CORP - Form 10-K405

determine our requirements for components and materials. It is very important that we accurately predict both the demand for our product and the lead times required to obtain the necessary components and materials. Lead times for components vary significantly and depend on numerous factors, including the specific supplier, the size of the order, contract terms and current market demand for such components. If we overestimate the demand for our product, we may have excess inventory, which would increase our costs. If we underestimate demand for our products and, consequently, our component and material requirements, we may have inadequate inventory, which could interrupt our manufacturing, delay delivery of our product to our customers and result in the loss of customer sales. Any of these occurrences would negatively impact our business and operating results.

IF OUR FACILITIES WERE TO EXPERIENCE CATASTROPHIC LOSS, OUR OPERATIONS WOULD BE SERIOUSLY HARMED. Our facilities could be subject to a catastrophic loss such as fire, flood or earthquake. All of our research and development activities, manufacturing, our corporate headquarters and other critical business operations are located near major earthquake faults in Mountain View, California. Any such loss at any of our facilities could disrupt our operations, delay production, shipments and revenue and result in large expense to repair and replace our facilities.

WE MAY NEED ADDITIONAL CAPITAL, WHICH MAY NOT BE AVAILABLE AND OUR ABILITY TO GROW MAY BE LIMITED AS A RESULT. We believe that our existing cash balances, available-for-sale securities, credit facilities and cash flow expected to be generated from future operations, will be sufficient to meet our capital requirements at least through the next 12 months. However, we may be required, or could elect, to seek additional funding prior to that time. The development and marketing of new products and associated support personnel requires a significant commitment of resources. If cash from available sources is insufficient, we may need additional capital, which may not be available on favorable terms, if at all. If we cannot raise funds on acceptable terms we may not be able to develop or enhance our products, take advantage of future opportunities or respond to competitive pressures or unanticipated requirements. Any inability to raise additional capital when we require it would seriously harm our business.

OUR STOCK PRICE IS VOLATILE. The trading price of our Common Stock has been subject to wide fluctuations in response to a variety of factors, some of which are beyond our control, including:

- Quarterly variations in operating results;
- Changes in financial estimates by securities analysts;
- Announcements by us or our competitors of new products or of significant clinical achievements
- Changes in market valuations of other similar companies; and
- Any deviations in our net sales or levels of profitability from levels expected by securities analysts.

In addition, the stock market has recently experienced extreme volatility that has often been unrelated to the performance of particular companies. These broad market fluctuations could have a significant impact on the market price of our common stock regardless of our performance.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

QUANTITATIVE DISCLOSURES

Edgar Filing: IRIDEX CORP - Form 10-K405

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 29, 2001.

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 2002 and the interest rates are primarily fixed.

QUALITATIVE DISCLOSURES

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

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

-35-

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 it's 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 29, 2001 and December 30, 2000 and the consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the three years in the period ended December 29, 2001, 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.

-36-

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 operations, of stockholders' equity, of cash flows,

Edgar Filing: IRIDEX CORP - Form 10-K405

and of comprehensive income (loss) present fairly, in all material respects, the financial position of IRIDEX Corporation and its Subsidiaries (the "Company") at December 29, 2001 and December 30, 2000 and the results of their operations, their cash flows, and of comprehensive income (loss) for each of the three years in the period ended December 29, 2001 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 59 presents fairly, in all material respects, the information set forth therein when read in conjunction with the related financial statements. These financial statements and financial statement schedule are the responsibility of the Company's management; our responsibility is to express an opinion on these consolidated financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

San Jose, California
January 25, 2002

-37-

IRIDEX CORPORATION

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

| | December 29, 2001 | Dec 2 |
|---|----------------------|----------|
| | ----- | --- |
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 4,613 | \$ |
| Available-for-sale securities | 4,489 | |
| Accounts receivable, net of allowance for doubtful accounts of \$318 in 2001 and \$481 in 2000 | 8,066 | |
| Inventories, net | 12,562 | |
| Prepays and other current assets | 599 | |
| | ----- | --- |
| Total current assets | 30,329 | 3 |
| Property and equipment, net | 1,535 | |
| Deferred income taxes | 1,924 | |
| | ----- | --- |
| Total assets | \$ 33,788 | \$ 3 |
| | ===== | === |

LIABILITIES AND STOCKHOLDERS' EQUITY

Edgar Filing: IRIDEX CORP - Form 10-K405

| | | |
|--|-----------|-------|
| Current liabilities: | | |
| Accounts payable | \$ 1,176 | \$ |
| Accrued expenses | 2,779 | |
| | ----- | ---- |
| Total liabilities | 3,955 | |
| | ----- | ---- |
| 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: 6,815,672 shares in 2001 and 6,700,862 shares in 2000 | 69 | |
| Additional paid-in capital | 23,417 | 2 |
| Accumulated other comprehensive income | 3 | |
| Treasury Stock | | |
| Outstanding: 103,000 shares in 2001 and 76,000 shares in 2000 | (430) | |
| Retained earnings | 6,774 | |
| | ----- | ---- |
| Total stockholders' equity | 29,833 | 3 |
| | ----- | ---- |
| Total liabilities and stockholders' equity | \$ 33,788 | \$ 3 |
| | ===== | ===== |

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

-38-

IRIDEX CORPORATION

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

| | YEAR ENDED DECEMBER 29, 2001 | Y DE |
|---|------------------------------------|---------|
| | ----- | ---- |
| Sales | \$ 27,275 | |
| Cost of sales | 14,205 | |
| | ----- | |
| Gross profit | 13,070 | |
| | ----- | |
| Operating expenses: | | |
| Research and development | 4,808 | |
| Sales, general and administrative | 10,251 | |
| | ----- | |
| Total operating expenses | 15,059 | |
| | ----- | |

Edgar Filing: IRIDEX CORP - Form 10-K405

| | |
|---|------------|
| Income (loss) from operations | (1,989) |
| Interest income | 378 |
| Other income, net | 48 |
| | ----- |
| Income (loss) before income taxes | (1,563) |
| Benefit from (provision for) income taxes | 962 |
| | ----- |
| Income (loss) from continuing operations | (601) |
| Income (loss) from operations of discontinued Laser Research segment (net of applicable income tax benefit (provision) of \$124, \$(131) and \$(80), respectively in 2001, 2000 and 1999) ... | (204) |
| Income (loss) on disposal of Laser Research segment, including (net of applicable income tax benefit of \$315, \$0 and \$0, respectively in 2001, 2000 and 1999) | (468) |
| | ----- |
| Net income (loss) | \$ (1,273) |
| | ===== |
| Basic net income (loss) per share: | |
| Continuing operations | \$ (0.09) |
| Discontinued operations | (0.10) |
| | ----- |
| Basic net income (loss) per common share | \$ (0.19) |
| | ===== |
| Diluted net income (loss) per share: | |
| Continuing operations | \$ (0.09) |
| Discontinued operations | (0.10) |
| | ----- |
| Diluted net income (loss) per common share | \$ (0.19) |
| | ===== |
| Shares used in net income (loss) per common share basic calculations | 6,757 |
| | ===== |
| Shares used in net income (loss) per common share diluted calculations | 6,757 |
| | ===== |

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

-39-

IRIDEX CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(IN THOUSANDS, EXCEPT SHARE DATA)

| | Common Stock | | Additional | Treasury | Accumula Other Comprehen |
|---|--------------|--------|--------------------|----------|--------------------------------|
| | Shares | Amount | Paid-in Capital | Stock | Income (L |
| | ----- | ----- | ----- | ----- | ----- |
| Balances, January 2, 1999..... | 6,506,010 | \$65 | \$21,800 | | \$ 7 |
| Issuance of Common Stock under Stock Option Plan..... | 51,544 | | 107 | | |
| Issuance of Common Stock under Employee Stock Purchase Plan..... | 58,804 | 1 | 217 | | |
| Purchase of Treasury Stock..... | (76,000) | | | (315) | |
| Change in unrealized gains on available-for-sale securities... | | | | | (9 |

Edgar Filing: IRIDEX CORP - Form 10-K405

| | | | | | |
|--|-----------|------|----------|----------|-------|
| Net income..... | ----- | --- | ----- | ----- | --- |
| Balances, January 1, 2000..... | 6,540,358 | 66 | 22,124 | (315) | (2) |
| Issuance of Common Stock under Stock Option Plan..... | 120,173 | 1 | 317 | | |
| Issuance of Common Stock under Employee Stock Purchase Plan..... | 40,331 | | 242 | | |
| Stock compensation expense..... | | | 8 | | |
| Change in unrealized gains on available-for-sale securities... | | | | | 12 |
| Net income..... | ----- | --- | ----- | ----- | --- |
| Balances, December 30, 2000..... | 6,700,862 | 67 | 22,691 | (315) | 10 |
| Issuance of Common Stock under Stock Option Plan..... | 74,942 | 1 | 99 | | |
| Issuance of Common Stock under Employee Stock Purchase Plan.... | 66,868 | 1 | 255 | | |
| Purchase of Treasury Stock..... | (27,000) | | | (115) | |
| Tax Benefit of Employee Stock Option Plan..... | | | 372 | | |
| Change in unrealized gains on available-for-sale securities... | | | | | (7) |
| Net loss..... | ----- | --- | ----- | ----- | --- |
| Balances, December 29, 2001..... | 6,815,672 | \$69 | \$23,417 | \$ (430) | \$ 3 |
| | ===== | === | ===== | ===== | ===== |

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

-40-

IRIDEX CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

| | YEAR ENDED DECEMBER 29, 2001 ----- |
|---|---|
| Cash flows from operating activities: | |
| Net income (loss) | \$ (1,273) |
| Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities: | |
| Depreciation and amortization | 859 |
| Tax Benefit of Employee Stock Option Plan | 372 |
| Stock compensation expense | -- |
| Provision for doubtful accounts | (163) |
| Provision for inventories | 343 |
| Deferred income taxes | (332) |
| Amortization of intangible asset | |
| Changes in assets and liabilities: | |
| Accounts receivable | 107 |
| Inventories | (3,184) |
| Prepays and other current assets | 206 |

Edgar Filing: IRIDEX CORP - Form 10-K405

| | |
|---|----------|
| Accounts payable | (232) |
| Accrued expenses | (338) |
| | ----- |
| Net cash provided by (used in) operating activities | (3,635) |
| | ----- |
| Cash flows from investing activities: | |
| Purchases of available-for-sale securities | (4,489) |
| Proceeds from maturity of available-for-sale securities | 2,989 |
| Acquisition of property and equipment | (491) |
| | ----- |
| Net cash provided by (used in) investing activities | (1,991) |
| | ----- |
| Cash flows from financing activities: | |
| Purchase of Treasury Stock | (115) |
| Issuance of Common Stock under stock purchase and option plans | 356 |
| | ----- |
| Net cash provided by financing activities | 241 |
| | ----- |
| Net (decrease) increase in cash and cash equivalents | (5,385) |
| Cash and cash equivalents, beginning of year | 9,998 |
| | ----- |
| Cash and cash equivalents, end of year | \$ 4,613 |
| | ===== |
| SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION: | |
| Cash paid during the period for: | |
| Income taxes | \$ 12 |
| SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING ACTIVITIES: | |
| Change in unrealized gains (losses) on available-for-sale securities | \$ (7) |

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

-41-

IRIDEX CORPORATION
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(IN THOUSANDS)

| | YEAR ENDED DECEMBER 29, 2001 | YEAR ENDED DECEMBER 30, 2000 | YEAR ENDED JANUARY 1, 2000 |
|--|------------------------------------|------------------------------------|----------------------------------|
| | ----- | ----- | ----- |
| Net income (loss) | \$ (1,273) | \$2,416 | \$ 1,618 |
| Other comprehensive income: | | | |
| Changes in unrealized gains (losses) on available-for-sale securities | (7) | 12 | (9) |
| | ----- | ----- | ----- |
| Comprehensive income (loss) | \$ (1,280) | \$2,428 | \$ 1,609 |
| | ===== | ===== | ===== |

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

IRIDEX CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. BUSINESS OF THE COMPANY

Description of Business

IRIDEX Corporation is a leading worldwide provider of semiconductor-based laser systems used to treat eye diseases in ophthalmology and skin afflictions 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 29, 2001 and 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 is computed using the straight-line method over the estimated useful life of the related assets, typically three years.

Edgar Filing: IRIDEX CORP - Form 10-K405

Revenue Recognition

Revenue from product sales is recognized upon receipt of a purchase order and product shipment provided no significant obligations remain and collection of the receivables is deemed probable. Up-front fees 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. We analyze historical returns, current economic trends and changes in customer demand and acceptance of our products when evaluating the adequacy of the sales returns allowance. Significant management judgements and estimates must be made and used in connection with establishing the sales returns and other allowances in any accounting period.

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 2001, 2000 and 1999 were \$408,000, \$478,000 and \$359,000, respectively.

Fair Value of Financial Instruments

Carrying amounts of our financial instruments including cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate fair 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.

-44-

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

Edgar Filing: IRIDEX CORP - Form 10-K405

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").

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 29, 2001, December 30, 2000 and January 1, 2000 no customer accounted for greater than 10% of revenue. As of December 29, 2001, 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.

-45-

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. As a result of Iridex's disposal of its Laser Research segment in 2001, the Company's previously reported consolidated financial statements for 2000 and 1999 have been reclassified to present the

Edgar Filing: IRIDEX CORP - Form 10-K405

discontinued Laser Research segment operations separate from continuing operations. (See Note 11.)

Fiscal Year

Our fiscal year covers a 52 or 53 week period and ends on the Saturday nearest December 31. Fiscal year 1999, 2000 and 2001 all included 52 weeks.

Net Income (loss) per Share

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

Recent Accounting Pronouncements

In July 2001, the Financial Accounting Standards Board issued SFAS No. 141 "Business Combinations," which establishes financial accounting and reporting for business combinations and supersedes APB Opinion No. 16, Business Combinations, and FASB Statement No. 38, Accounting for Preacquisition Contingencies of Purchased Enterprises. It requires that all business combinations in the scope of this Statement are to be accounted for using one method, the purchase method. The provisions of this Statement apply to all business combinations initiated after June 30, 2001, and also applies to all business combinations accounted for using the purchase method for which the date of acquisition is July 1, 2001, or later. The Company believes that adoption of the standard will not have a material effect on the financial position or results of operations of the Company.

In July 2001, the Financial Accounting Standards Board issued SFAS No. 142 "Goodwill and Other Intangible Assets," which establishes financial accounting and reporting for acquired goodwill and other

-46-

intangible assets and supercedes APB Opinion No. 17, Intangible Assets. It addresses how intangible assets that are acquired individually or with a group of other assets (but not those acquired in a business combination) should be accounted for in financial statements upon their acquisition, after they have been initially recognized in the financial statements. The provisions of this Statement are effective starting with fiscal years beginning after December 15, 2001. The Company believes that SFAS No. 142 will not have a material effect on the financial position or results of operation of the Company.

In October 2001, the Financial Accounting Standards Board issued SFAS 144 "Accounting for the Impairment or Disposal of Long-Lived Assets" that develops one accounting model for long lived assets that are to be disposed of by sales and requires long-lived assets that are to be disposed of by sales be measured at the lower of book value or fair value less cost to sell. Additionally, SFAS No. 144 expands the scope of discontinued operations to include all components of an entity with operations that (1) can be distinguished from the rest of the entity and (2) will be eliminated from the ongoing operations of the entity in a disposal transaction. SFAS No. 144 supercedes SFAS No. 121 "Accounting for the Impairment of Long-Lived Assets to be Disposed Of." SFAS No. 144 applies to all long-lived assets (including discontinued operations) and consequently amends Accounting Principles Board Opinion No. 30 (APB 30), Reporting Results of Operations Reporting the Effects

Edgar Filing: IRIDEX CORP - Form 10-K405

of Disposal of a segment of a business. Management does not expect the adoption of SFAS 144 to have a material impact on the Company's financial position and results of operations.

3. BALANCE SHEET DETAIL

Available-for-sale securities (in thousands):

| | COST | UNREALIZED GAINS | ESTIMATED FAIR VALUE |
|--|----------|---------------------|-------------------------|
| As of December 29, 2001, available-for-sale securities consisted of the following: | | | |
| Government agencies..... | \$ 4,486 | \$ 3 | \$ 4,489 |
| As of December 30, 2000, available-for-sale securities consisted of the following: | | | |
| Government agencies..... | \$ 2,986 | \$ 10 | \$ 2,996 |

There were no realized capital gains or losses recognized in 2001, 2000 and 1999.

-47-

| | DECEMBER 29, 2001 | DECEMBER 30, 2000 |
|--|----------------------|----------------------|
| (IN THOUSANDS) | | |
| Inventories: | | |
| Raw materials and work in process..... | \$ 8,078 | \$ 6,168 |
| Finished goods..... | 4,484 | 3,553 |
| | ----- | ----- |
| Total inventories..... | \$12,562 | \$ 9,721 |
| | ===== | ===== |
| Property and Equipment: | | |
| Equipment..... | \$ 3,202 | \$ 3,229 |
| Leasehold improvements..... | 1,872 | 1,829 |
| Less: accumulated depreciation and amortization..... | (3,539) | (3,155) |
| | ----- | ----- |
| Property and equipment, net..... | \$ 1,535 | \$ 1,903 |
| | ===== | ===== |
| Accrued Expenses: | | |
| Accrued payroll, vacation and related expenses..... | \$ 870 | \$ 1,057 |
| Accrued warranty..... | 582 | 728 |
| Income taxes payable..... | -- | 404 |
| Sales and use tax payable..... | 266 | 195 |
| Deferred revenue..... | 329 | 146 |
| Other accrued expenses..... | 732 | 587 |
| | ----- | ----- |
| Total accrued expenses..... | \$ 2,779 | \$ 3,117 |
| | ===== | ===== |

Edgar Filing: IRIDEX CORP - Form 10-K405

4. BANK BORROWINGS

We have a revolving line of credit agreement with a bank expiring on October 5, 2002, which provides for borrowings of up to \$4.0 million at the bank's prime rate (4.75% at December 29, 2001). 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 29, 2001.

5. COMMITMENTS AND CONTINGENCIES

Lease Agreements

We lease our operating facilities under a noncancelable operating lease. The lease, which expires in 2002, was renewed for two years. Rent expense, net of sublease income, totaled \$498,000, \$289,000 and \$282,000 for the years ended December 29, 2001, December 30, 2000 and January 1, 2000 respectively. Rental income related to a facility sublease was \$11,000, \$262,000 and \$183,000 for the years ended December 29, 2001, December 30, 2000 and January 1, 2000, respectively.

Future minimum lease payments under current operating leases at December 29, 2001 are summarized as follows (in thousands):

| Fiscal Year ----- | Operating Lease Payments ----- |
|----------------------|-----------------------------------|
| 2002 | 650 |
| 2003 | 687 |
| 2004 | 115 |
| | ----- |
| | \$1,452 |
| | ===== |

-48-

License Agreements

The Company is obligated to pay royalties equivalent to 5% and 7.5% of sales on certain products under certain license agreements. Royalty expense was \$85,000, \$21,000 and \$42,000 for the years ended December 29, 2001, December 30, 2000 and January 1, 2000, 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

Edgar Filing: IRIDEX CORP - Form 10-K405

Our Articles of Incorporation authorize 2,000,000 shares of undesignated preferred stock. Preferred Stock may be issued from time to time in one or more series. As of December 29, 2001, we had no preferred stock issued and outstanding.

TREASURY STOCK

In December 1998, we instituted a stock repurchase program whereby up to 150,000 shares of our Common Stock may be repurchased in the open market. We plan to utilize all of the reacquired shares for reissuance in connection with our employee stock programs. We repurchased 76,000 shares of Common Stock for \$315,000 in 1999. In 2000, no shares of Common Stock were repurchased. In 2001, we repurchased 27,000 shares of Common Stock for \$115,000.

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

-49-

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

Edgar Filing: IRIDEX CORP - Form 10-K405

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 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.

-50-

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

| | OUTSTANDING OPTIONS | | | |
|----------------------------------|----------------------------------|---------------------|--------------------|---------------------------------------|
| | SHARES AVAILABLE FOR GRANT | NUMBER OF SHARES | AGGREGATE PRICE | WEIGHTED AVERAGE EXERCISE PRICE |
| Balances, January 2, 1999 | 188,744 | 1,317,501 | \$ 5,419 | \$4.11 |
| Additional shares reserved | 150,000 | -- | -- | -- |
| Options granted | (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 | (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 |
| | ----- | ----- | ----- | |

Edgar Filing: IRIDEX CORP - Form 10-K405

| | | | | |
|-----------------------------------|-----------|-----------|----------|--------|
| Balances, December 30, 2000 | 163,812 | 1,490,313 | \$ 8,292 | \$5.56 |
| Additional shares reserved | 290,000 | -- | -- | -- |
| Options granted | (368,050) | 368,050 | 1,512 | 4.11 |
| Options exercised | | (74,942) | (100) | 1.61 |
| Options expired | (29,068) | | | |
| Options terminated | 126,604 | (126,604) | (873) | 7.07 |
| | ----- | ----- | ----- | |
| Balances, December 29, 2001 | 183,298 | 1,656,817 | \$ 8,831 | \$5.34 |
| | ===== | ===== | ===== | |

The following table summarizes information with respect to stock options outstanding at December 29, 2001:

| RANGE OF EXERCISE PRICES | OPTIONS OUTSTANDING | | | OPTIONS EXERCISABLE | |
|--------------------------|--------------------------------|---|---------------------------------|--------------------------------|---------------------------------|
| | NUMBER OUTSTANDING AT 12/29/01 | WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE (YEARS) | WEIGHTED AVERAGE EXERCISE PRICE | NUMBER EXERCISABLE AT 12/29/01 | WEIGHTED AVERAGE EXERCISE PRICE |
| \$0.16 - \$2.00 | 136,549 | 2.90 | \$1.17 | 136,549 | \$1.17 |
| \$3.71 - \$3.71 | 203,800 | 9.55 | 3.71 | 0 | 0.00 |
| \$3.90 - \$3.94 | 23,000 | 8.63 | 3.91 | 6,132 | 3.94 |
| \$4.00 - \$4.00 | 457,086 | 5.77 | 4.00 | 387,425 | 4.00 |
| \$4.03 - \$4.88 | 199,357 | 8.08 | 4.35 | 78,321 | 4.42 |
| \$5.00 - \$5.75 | 178,925 | 6.99 | 5.46 | 110,825 | 5.55 |
| \$6.25 - \$8.88 | 203,500 | 6.47 | 8.27 | 150,603 | 8.23 |
| \$9.00 - \$9.25 | 189,600 | 8.29 | 9.09 | 80,246 | 9.10 |
| \$9.50 - \$12.75 | 57,500 | 8.66 | 11.18 | 14,828 | 10.92 |
| \$14.88 - \$14.88 | 7,500 | 4.50 | 14.88 | 7,500 | 14.88 |
| | ----- | | | ----- | |
| \$0.16 - \$14.88 | 1,656,817 | 6.92 | 5.34 | 972,249 | 5.08 |
| | ===== | | | ===== | |

At December 30, 2000 and January 1, 2000 options to purchase 762,123 and 624,025 shares of Common Stock were exercisable at weighted average exercise prices of \$4.29 and \$3.53, respectively.

-51-

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:

| 2001 | | 2000 | | 1999 | |
|---------|---------|---------|---------|---------|---------|
| GROUP A | GROUP B | GROUP A | GROUP B | GROUP A | GROUP B |
| ----- | ----- | ----- | ----- | ----- | ----- |

Edgar Filing: IRIDEX CORP - Form 10-K405

| | | | | | | |
|--|--------|--------|--------|--------|--------|--------|
| Risk-free Interest Rates.... | 4.45% | 4.40% | 6.00% | 6.19% | 5.58% | 5.34% |
| Expected Life from Date of Vesting..... | 3 yrs. | 2 yrs. | 3 yrs. | 2 yrs. | 3 yrs. | 2 yrs. |
| Volatility..... | 0.90 | 0.90 | 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 2001, 2000 and 1999 was \$2.82, \$5.96 and \$3.37, 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 2001, 2000 and 1999:

| | 2001 | 2000 | 1999 |
|------------------------------|----------|----------|----------|
| | ----- | ----- | ----- |
| Risk-free Interest Rates.... | 4.63% | 5.67% | 4.91% |
| Expected Life..... | 0.5 year | 0.5 year | 0.5 year |
| Volatility..... | 0.90 | 0.78 | 0.78 |
| Dividend Yield..... | -- | -- | -- |

The weighted average grant-date fair value per share of those purchase rights granted in 2001, 2000 and 1999 was \$2.11, \$2.94 and \$1.55, respectively.

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

| | 2001 | 2000 | 1999 |
|--|---|----------|----------|
| | ----- | ----- | ----- |
| | (amounts in thousands except per share data) | | |
| Net income (loss) -- as reported | \$ (1,273) | \$ 2,416 | \$ 1,618 |
| Net income (loss) -- pro forma | \$ (2,000) | \$ 1,640 | \$ 768 |
| Net income (loss) per common share -- as reported | \$ (0.19) | \$ 0.36 | \$ 0.25 |
| Net income (loss) per common share -- pro forma | \$ (0.30) | \$ 0.25 | \$ 0.12 |
| Diluted net income (loss) per common share -- as reported | \$ (0.19) | \$ 0.33 | \$ 0.24 |
| Diluted net income (loss) per common share -- pro forma | \$ (0.30) | \$ 0.23 | \$ 0.11 |

Edgar Filing: IRIDEX CORP - Form 10-K405

We have a plan known as the IRIS Medical Instruments 401(k) trust to provide retirement benefits through the deferred salary deductions for substantially all employees. Employees may contribute up to 15% of their annual compensation to the plan, limited to a maximum amount set by the Internal Revenue Service. The plan also provides for Company contributions at the discretion of the Board of Directors. On April 1, 2000 the Company commenced a Company match for the 401(k) in the amount of 50% of employee contributions up to an annual maximum of \$1,000 per year. The Company contributions in fiscal 2001 totaled \$99,000. The Company contributions in fiscal 2000 totaled \$64,000. No contributions were made in fiscal 1999.

8. INCOME TAXES

The provision for income taxes includes:

| | YEAR ENDED DECEMBER 29, 2001 | YEAR ENDED DECEMBER 30, 2000 | YEAR ENDED JANUARY 1, 2000 |
|---|------------------------------------|------------------------------------|----------------------------------|
| | ----- | ----- | ----- |
| | (IN THOUSANDS) | | |
| Current: | | | |
| Federal | \$(750) | \$855 | \$1,242 |
| State | -- | 28 | 286 |
| | ----- | ----- | ----- |
| | (750) | 883 | 1,528 |
| | ----- | ----- | ----- |
| Deferred: | | | |
| Federal | (184) | (96) | (613) |
| State | (28) | 22 | (233) |
| | ----- | ----- | ----- |
| | (212) | (74) | (846) |
| | ----- | ----- | ----- |
| Income tax (benefit) provision | \$ (962) | \$809 | \$ 682 |
| | ===== | ===== | ===== |

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

| | YEAR ENDED DECEMBER 29, 2001 | YEAR ENDED DECEMBER 30, 2000 | YEAR ENDED JANUARY 1, 2000 |
|---|------------------------------------|------------------------------------|----------------------------------|
| | ----- | ----- | ----- |
| Income tax provision (benefit) at statutory rate | (34)% | 34% | 34% |
| State income taxes, net of federal benefit | (5)% | 6% | 6% |
| Tax exempt interest | (3)% | (3)% | (3)% |
| Nondeductible permanent differences | 4% | 0% | 0% |
| Research and experimental credits | (28)% | (10)% | (10)% |
| Other | 4% | 1% | 5% |
| | ----- | ----- | ----- |
| Effective tax rate | (62)% | 28% | 32% |
| | ===== | ===== | ===== |

In 2001, the Company's effective rate was a benefit of 62% primarily as a

Edgar Filing: IRIDEX CORP - Form 10-K405

result of the level of tax credits for research and development activities relative to the loss for 2001.

-53-

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 29, 2001 | DECEMBER 30, 2000 |
|---|----------------------|----------------------|
| | ----- | ----- |
| Fixed assets | \$ 304 | \$ 487 |
| Accrued liabilities | 419 | 467 |
| Allowance for excess and obsolete inventories | 287 | 151 |
| Research credit | 437 | 329 |
| State tax | 1 | -- |
| Allowance for doubtful accounts | 127 | 186 |
| Other | 349 | (28) |
| | ----- | ----- |
| Net deferred tax asset | \$1,924 | \$ 1,592 |
| | ===== | ===== |

9. MAJOR CUSTOMERS AND BUSINESS SEGMENTS

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

In the years ended December 29, 2001, December 30, 2000 and January 1, 2000, no customer individually accounted for more than 10% of our revenue.

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

| | DECEMBER 29, 2001 | DECEMBER 30, 2000 | JANUARY 1, 2000 |
|------------------------|----------------------|----------------------|--------------------|
| | ----- | ----- | ----- |
| United States | \$16,004 | \$21,133 | \$16,134 |
| Europe | 5,530 | 5,475 | 4,611 |
| Rest of Americas | 809 | 1,283 | 1,689 |
| Asia/Pacific Rim | 4,932 | 4,947 | 3,957 |
| | ----- | ----- | ----- |
| | \$27,275 | \$32,838 | \$26,391 |
| | ===== | ===== | ===== |

Revenues are attributed to countries based on location of customers.

In the years ended December 29, 2001, January 1, 2000 and January 1, 2000, no country individually accounted for more than 10% of our sales, except for the United States, which accounted for 58.7 % of sales in 2001, 64.4% in

Edgar Filing: IRIDEX CORP - Form 10-K405

2000 and 61.1% in 1999.

-54-

Information on reportable segments for the three years ended December 29, 2001, December 30, 2000 and January 1, 2000 is as follows:

| | YEAR ENDED DECEMBER 29, 2001 | | | YEAR ENDED DECEMBER 30, 2000 | | | Ophth |
|------------------------------|-------------------------------------|-----------------------------------|------------|-------------------------------------|-----------------------------------|----------|-------|
| | Ophthalmology Medical Devices | Dermatology Medical Devices | Total | Ophthalmology Medical Devices | Dermatology Medical Devices | Total | |
| Sales | \$20,922 | \$6,353 | \$ 27,275 | \$27,065 | \$5,773 | \$32,838 | |
| Direct Cost of Goods Sold | 6,772 | 2,595 | 9,367 | 7,796 | 2,051 | 9,847 | |
| Direct Gross Margin | 14,150 | 3,758 | 17,908 | 19,269 | 3,722 | 22,991 | |
| Total Unallocated Costs | -- | -- | 19,471 | -- | -- | 20,102 | |
| Pre-tax income (loss) | | | \$ (1,563) | | | \$ 2,889 | |

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

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

-55-

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 29, 2001 | YEAR END DECEMBER 2000 |
|---|------------------------------------|------------------------------|
| Numerator -- Net income (loss) per common share and per diluted common share | | |
| Net income (loss) | \$ (1,273) | \$2,41 |
| Denominator -- Net income (loss) per common share | | |
| Weighted average common stock outstanding | 6,757 | 6,63 |
| Net income (loss) per common share | \$ (0.19) | \$ 0.3 |
| Denominator -- Diluted net income (loss) per common share | | |
| Weighted average common stock outstanding | 6,757 | 6,63 |

Edgar Filing: IRIDEX CORP - Form 10-K405

| | | |
|--|-----------|--------|
| Effect of dilutive securities | -- | 64 |
| Weighted average common stock options | ----- | ----- |
| Total weighted average stock and options outstanding | 6,757 | 7,28 |
| | ===== | ===== |
| Diluted net income (loss) per common share | \$ (0.19) | \$ 0.3 |
| | ===== | ===== |

During 2000 and 1999, there were 62,930, and 431,077 outstanding options to purchase shares, respectively, at a weighted average exercise price of \$9.82, and \$5.28 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. During 2001, options to purchase 1,656,817 shares at a weighted average exercise price of \$5.34 were outstanding but were not included in the computation of diluted net loss per common share because their effect was antidilutive. These options could dilute earnings per share in future periods.

11. SELECTED QUARTERLY FINANCIAL DATA, (UNAUDITED)

| | QUARTER | | |
|--|-------------------------------------|---------|---------|
| | FIRST | SECOND | THIRD |
| | ----- | ----- | ----- |
| | (IN THOUSANDS, EXCEPT PER SHARE AMO | | |
| Year Ended December 29, 2001 | | | |
| Sales | \$ 5,735 | \$7,088 | \$6,750 |
| Gross profit | \$ 2,363 | \$3,697 | \$3,498 |
| Income (loss) from continuing operations | \$ (924) | \$ 11 | \$ 171 |
| Income (loss) from discontinued operations | \$ (893) | \$ -- | \$ -- |
| Net income (loss) | \$ (1,817) | \$ 11 | \$ 171 |
| Net income (loss) per common share | \$ (0.27) | \$ 0.00 | \$ 0.03 |
| Diluted income (loss) from continuing operations | | | |
| per common share | \$ (0.14) | \$ 0.00 | \$ 0.02 |
| Diluted income (loss) from discontinued operations | | | |
| per common share | \$ (0.13) | \$ 0.00 | \$ 0.00 |
| Diluted net income (loss) per common share | \$ (0.27) | \$ 0.00 | \$ 0.02 |
| Year Ended December 30, 2000 | | | |
| Sales(1) | \$ 7,996 | \$8,818 | \$8,213 |
| Gross profit(1) | \$ 4,659 | \$5,147 | \$4,441 |
| Income (loss) from continuing operations | \$ 644 | \$ 790 | \$ 422 |
| Income (loss) from discontinued operations | \$ 109 | \$ (32) | \$ 172 |
| Net income (loss) | \$ 711 | \$ 716 | \$ 561 |
| Net income (loss) per common share | \$ 0.11 | \$ 0.11 | \$ 0.08 |
| Diluted income (loss) from continuing operations | | | |
| per common share | \$ 0.09 | \$ 0.10 | \$ 0.06 |
| Diluted income (loss) from discontinued operations | | | |
| per common share | \$ 0.00 | \$ 0.00 | \$ 0.02 |
| Diluted net income (loss) per common share | \$ 0.09 | \$ 0.10 | \$ 0.08 |

(1) Sales and Cost of Sales amounts for 2000 have been revised to reflect impact of discontinued operations.

12. DISCONTINUED OPERATIONS

In April 2001, we discontinued our Laser Research segment. In the first quarter of 2001, we recorded a loss of \$893,000 (net of a \$542,000 tax benefit). In the fourth quarter of 2001, we adjusted the loss on discontinued operations

Edgar Filing: IRIDEX CORP - Form 10-K405

to \$672,000 (net of a \$439,000 tax benefit). Revenues for

-56-

this segment were \$599,000 for 2000 and \$460,000 for 1999. Costs and operating expenses of the Laser Research segment were \$132,000 for 2000 and \$209,000 for 1999. Sales, general and administrative costs and indirect costs of manufacturing historically were not allocated to the Laser Research segment.

12. SUBSEQUENT EVENTS

On January 13, 2002 a customer announced that the phase III clinical trial of SnET2, a photodynamic drug activated by the OcuLight 664 laser system for use in the treatment of wet AMD, did not meet the primary efficacy endpoint of the study. As a result, the Company included a pretax charge in the fourth quarter to cost of sales of \$287,000 to reserve inventory associated with the OcuLight 664 system.

ITEM 9. DISAGREEMENTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

-57-

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 for our 2002 Annual Meeting of Stockholders, 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 5, 2002.

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 our 2002 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.

-58-

Edgar Filing: IRIDEX CORP - Form 10-K405

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:

1. FINANCIAL STATEMENTS

Report of Independent Accountants.....
Consolidated Balance Sheets as of December 29, 2001 and December 30, 2000.....
Consolidated Statements of Operations for the years ended December 29, 2001, December 30, 2000 and January 1, 2000.....
Consolidated Statements of Stockholders' Equity for the years ended December 29, 2001, December 30, 2000 and January 1, 2000.....
Consolidated Statements of Cash Flows for the years ended December 29, 2001, December 30, 2000 and January 1, 2000.....
Consolidated Statements of Comprehensive Income (Loss) for the years ended December 29, 2001, December 30, 2000 and January 1, 2000.....
Notes to Consolidated Financial Statements.....

2. FINANCIAL STATEMENT SCHEDULE

The following financial statement schedule is included in Item 14(d):
Schedule II -- Valuation and Qualifying Accounts.....

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. |

Edgar Filing: IRIDEX CORP - Form 10-K405

-59-

| Exhibits | Exhibit Title |
|-----------|--|
| ----- | ----- |
| 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 PricewaterhouseCoopers LLP, Independent Accountants. |
| 24.1 | Power of Attorney (See page 52). |

* 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

No reports on Form 8-K were filed during the fourth quarter of 2001.

TRADEMARK ACKNOWLEDGMENTS

IRIDEX, the IRIDEX logo, IRIS Medical, OcuLight, SmartKey, EndoProbe and Apex are our registered trademarks. IRIDERM, G-Probe, DioPexy, DioVet, TruFocus, TrueCW, UltraView, DioLite 532, Long Pulse, Micro Pulse, ScanLite Scanner, ColdTip Handpiece, Varispot Handpiece and Easy Fit product names are our trademarks. All other trademarks or trade names appearing in the Form 10-K are the property of their respective owners.

-60-

SIGNATURES

Edgar Filing: IRIDEX CORP - Form 10-K405

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange 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 29th day of March, 2002.

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

| | | |
|--|--|-----------------------|
| <p>/s/ Theodore A. Boutacoff ----- (Theodore A. Boutacoff)</p> | <p>President, Chief Executive Officer, and Director (Principal Executive Officer)</p> | <p>March 29, 2002</p> |
| <p>/s/ Robert Kamenski ----- (Robert Kamenski)</p> | <p>Chief Financial Officer and Vice President, Administration (Principal Financial and Accounting Officer)</p> | <p>March 29, 2002</p> |
| <p>/s/ James L. Donovan ----- (James L. Donovan)</p> | <p>Vice President, Corporate Business Development and Director</p> | <p>March 29, 2002</p> |
| <p>/s/ Robert K. Anderson ----- (Robert K. Anderson)</p> | <p>Director</p> | <p>March 29, 2002</p> |
| <p>/s/ Donald L. Hammond ----- (Donald L. Hammond)</p> | <p>Director</p> | <p>March 29, 2002</p> |
| <p>/s/ Joshua Makower ----- (Joshua Makower)</p> | <p>Director</p> | <p>March 29, 2002</p> |
| <p>/s/ John M. Nehra ----- (John M. Nehra)</p> | <p>Chairman of the Board</p> | <p>March 29, 2002</p> |

Edgar Filing: IRIDEX CORP - Form 10-K405

IRIDEX CORPORATION AND SUBSIDIARIES

VALUATION AND QUALIFYING ACCOUNTS (IN THOUSANDS)

| DESCRIPTION | BALANCE AT BEGINNING OF THE PERIOD | CHARGED TO COSTS AND EXPENSES | DEDUCTIONS |
|--|--|-------------------------------------|------------|
| Balance for the year ended January 1, 2000: | | | |
| Allowance for doubtful accounts receivable | \$327 | \$ 128 | \$ (59) |
| Provision for inventory | \$182 | \$ 197 | \$ (5) |
| Balance for the year ended December 30, 2000: | | | |
| Allowance for doubtful accounts receivable | \$396 | \$ 131 | \$ (46) |
| Provision for inventory | \$374 | \$ 285 | \$ -- |
| Balance for the year ended December 29, 2001: | | | |
| Allowance for doubtful accounts receivable | \$481 | \$ (163) | \$ -- |
| Provision for inventory | \$659 | \$ 65 | \$ -- |

-62-

EXHIBIT INDEX

| 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. |

Edgar Filing: IRIDEX CORP - Form 10-K405

| Exhibits | Exhibit Title |
|-----------|--|
| ----- | ----- |
| 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 52). |

* 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.