

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 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

77-0210467

(State or other jurisdiction of
incorporation or organization)

(I.R.S. employer
identification No.)

1212 TERRA BELLA AVENUE
MOUNTAIN VIEW, CALIFORNIA 94043-1824
(Address of principal executive offices, including zip code)

(650) 940-4700
(Registrant's telephone number, including area code)

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.

(1) Yes No ; (2) Yes No

The number of shares of Common Stock, \$.01 par value, issued and outstanding as of May 7, 2001 was 6,764,375.

IRIDEX CORPORATION

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IRIDEX CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS)
(UNAUDITED)

	MARCH 31, 2001	DECEMBER 30, 2000
ASSETS	----- (UNAUDITED)	-----

Current assets:		
Cash and cash equivalents	\$ 7,548	\$ 9,998
Available-for-sale securities	4,256	2,996
Accounts receivable, net	6,536	8,010
Inventories	9,268	9,721
Prepays and other current assets	895	805
	-----	-----
Total current assets	28,503	31,530
Property and equipment, net	1,908	1,903
Deferred income taxes	1,592	1,592
	-----	-----
Total assets	\$32,003	\$35,025
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY		

Current liabilities:		
Accounts payable	\$ 1,264	\$ 1,408
Accrued expenses	1,953	3,117
	-----	-----
Total liabilities	3,217	4,525
	-----	-----
Stockholders' equity:		
Common stock	68	67
Additional paid-in capital	22,790	22,691
Accumulated other comprehensive income	13	10
Retained earnings	5,915	7,732
	-----	-----
Total stockholders' equity	28,786	30,500
	-----	-----
Total liabilities and stockholders' equity ...	\$32,003	\$35,025
	=====	=====

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

IRIDEX CORPORATION
 CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
 (IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)
 (UNAUDITED)

	THREE MONTHS ENDED	
	MARCH 31, 2001	APRIL 1, 2000
Sales	\$ 5,735	\$ 8,021
Cost of sales	3,372	3,363
	2,363	4,658
Operating expenses:		
Research and development	1,312	1,088
Selling, general and administrative	2,798	2,646
	4,110	3,734
Operating income (loss) from continuing operations	(1,747)	924
Interest and other income (expense), net	140	136
	(1,607)	1,060
Income (loss) from continuing operations before benefit from (provision) for income taxes	(1,607)	1,060
Benefit from (provision) for income taxes	683	(334)
	(924)	726
Income (loss) from continuing operations	(924)	726
Discontinued operations (Note 4):		
Loss from operations of discontinued Laser Research segment (net of applicable income tax benefit of \$124 and \$0, respectively)	(204)	(15)
Loss on disposal of Laser Research segment, including provision of \$63 for operating losses during phase-out period (net of applicable income tax benefit of \$ 418)	(689)	--
	\$ (1,817)	\$ 711
Net income (loss)	\$ (1,817)	\$ 711
Basic net income (loss) per share:		
Continuing operations	\$ (0.14)	\$ 0.11
Discontinued operations	(0.13)	0.00
	\$ (0.27)	\$ 0.11
Basic net income (loss) per share:	\$ (0.27)	\$ 0.11
Shares used in per common shares basic calculations	6,712	6,619
	6,712	6,619
Diluted net income (loss) per share:		
Continuing operations	\$ (0.14)	\$ 0.10
Discontinued operations	(0.13)	0.00
	\$ (0.27)	\$ 0.10
Diluted net income (loss) per share:	\$ (0.27)	\$ 0.10
Shares used in per common share diluted calculations	6,712	7,374
	6,712	7,374

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

IRIDEX CORPORATION
 CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
 (IN THOUSANDS)
 (UNAUDITED)

	THREE MONTHS ENDED MARCH 31, 2001 -----	APRIL 1, 2000 -----
Cash flows from operating activities:		
Net income (loss)	\$ (1,817)	\$ 711
Adjustments to reconcile net income (loss) to net cash provided by (used in) continuing operations:		
Discontinued operations	564	--
Depreciation and amortization	204	261
Provision for doubtful accounts	--	42
Changes in operating assets and liabilities:		
Accounts receivable	1,466	(91)
Inventories	(221)	(94)
Prepays and other current assets	(93)	(21)
Accounts payable	(212)	16
Accrued expenses	(947)	(329)
Net cash provided by (used) in continuing operations	(1,056)	495
Cash flows from investing activities:		
Purchases of available-for-sale securities	(1,368)	(848)
Proceeds from maturity of available-for-sale securities	111	1,652
Acquisition of property and equipment	(237)	(155)
Net cash provided by (used) in investing activities	(1,494)	649
Cash flows from financing activities:		
Issuance of common stock, net	100	146
Net cash provided by financing activities	100	146
Net increase (decrease) in cash and cash equivalents	(2,450)	1,290
Cash and cash equivalents at beginning of period	9,998	9,645
Cash and cash equivalents at end of period	\$ 7,548	\$ 10,935
	=====	=====
SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Change in unrealized gains (losses) on available-for-sale securities	\$ 3	\$ (1)

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

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

	THREE MONTHS ENDED MARCH 31, 2001	APRIL 1, 2000
	-----	-----
Net income (loss).....	\$ (1,817)	\$711
Other comprehensive income (loss):		
Change in unrealized gain (loss) on available-for-sale securities.....	3	(1)
	-----	-----
Comprehensive income (loss).....	\$ (1,814)	\$710
	=====	=====

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

IRIDEX CORPORATION
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements of IRIDEX Corporation have been prepared in accordance with generally accepted accounting principles for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation have been included. The condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto, together with management's discussion and analysis of financial condition and results of operations, contained in our Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission on March 30, 2001. The results of operations for the three month period ended March 31, 2001 are not necessarily indicative of the results for the year ending December 29, 2001 or any future interim period.

2. INVENTORIES CONSIST OF THE FOLLOWING (IN THOUSANDS) :

	MARCH 31, 2001	DECEMBER 30, 2000
	-----	-----
	(unaudited)	
Raw materials and work in progress	\$5,073	\$6,168
Finished goods	4,195	3,553
	-----	-----
Total inventories	\$9,268	\$9,721
	=====	=====

3. COMPUTATIONS OF NET INCOME (LOSS) PER COMMON SHARE AND DILUTED NET INCOME (LOSS) PER COMMON SHARE

Basic and diluted net income (loss) 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.

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

	THREE MONTHS ENDED	
	MARCH 31, 2001	APRIL 1, 2000
	----- (unaudited)	----- (unaudited)
Numerator		
Income (loss) from continuing operations	\$ (924)	\$ 726
Income (loss) from discontinued operations	(893)	(15)
	-----	-----
Net income (loss)	\$ (1,817)	\$ 711
	=====	=====
Denominator -- Basic		
Weighted average common stock outstanding	6,712	6,619
	=====	=====
Basic income (loss) per share from continuing operations ...	\$ (0.14)	\$ 0.11
Basic income (loss) per share from discontinued operations .	(0.13)	(0.00)
	-----	-----
Basic income (loss) per share	\$ (0.27)	\$ 0.11
	=====	=====
Denominator -- Diluted		
Weighted average common stock outstanding	6,712	6,619
Effect of dilutive securities		
Weighted average common stock options	--	755
	-----	-----
Total weighted average stock and options outstanding	6,712	7,374
	=====	=====
Diluted income (loss) per share from continuing operations .	\$ (0.14)	\$ 0.10
Diluted income (loss) per share from discontinued operations	(0.13)	(0.00)
	-----	-----
Diluted income (loss) per share	\$ (0.27)	\$ 0.10
	=====	=====

For the three months ended April 1, 2000 all options outstanding were included in the computation of diluted net income (loss) per common share. For the three months ended March 31, 2001, options to purchase 625,406 shares at a weighted average exercise price of \$8.54 were outstanding, but were not included in the computation of diluted net income (loss) per common share because of the Company's net loss. These options could dilute earnings per share in future periods.

4. DISCONTINUED OPERATIONS

In April 2001, management decided to discontinue the Laser Research segment. Revenues of this segment totalled \$25,000 and \$196,000 for the three months ended March 31, 2001 and April 1, 2000, respectively. Costs and operating expenses of this segment totalled \$918,000 and \$211,000 for the three months ended March 31, 2001 and April 1, 2000, respectively. The total loss on discontinued operations of \$893,000 (net of a \$542,000 income tax benefit) for the three months ended March 31, 2001 consisted primarily of inventory and sales return costs. No assets or liabilities of the Laser Research segment remain and no proceeds are expected from the disposition of this segment.

5. INCOME TAXES

The Company uses the liability method to account for income taxes. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized. The provision for income taxes for the three month period ended April 1, 2000 was based on an estimated effective income tax rate of 32% for the fiscal year ending December 30, 2000. For the three months ended March 31, 2001, the effective tax benefit rate from continuing operations was 42%.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF
FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The discussion in Management's Discussion and Analysis of Financial Condition and Results of Operations contains trend analysis and other forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, such as those relating to level of international sales; future sales growth; timing of the introduction of the Apex 800; resolution of key component shortages; resolution of reimbursement issues; anticipated increases in manufacturing, research and development and sales, general and administrative expenses; anticipated decreases and fluctuations in gross margins; and future liquidity. Actual results could differ materially from those set forth in such forward-looking statements as a result of the factors set forth under "Factors That May Affect Future Operating Results" and other risks detailed in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 30, 2001 and detailed from time to time in the Company's reports filed with the Securities and Exchange Commission.

RESULTS OF OPERATIONS

The following table sets forth the percentage of net sales of certain items in our income statement for the periods indicated.

	THREE MONTHS ENDED MARCH 31, 2001	APRIL 1, 2000
	-----	-----
Sales	100.0%	100.0%
Cost of sales	58.8	41.9
	-----	-----
Gross profit	41.2	58.1
	-----	-----
Operating expenses:		
Research and development	22.9	13.6
Sales, general and administrative	48.8	33.0
	-----	-----
Total operating expenses	71.7	46.6
	-----	-----
Operating income (loss) from continuing operations	(30.5)	11.5
Other income, net	2.5	1.7
	-----	-----
Income (loss) from continuing operations before provision for income taxes	(28.0)	13.2
Benefit (provision) for income taxes	11.9	(4.2)
	-----	-----
Income (loss) from continuing Operations	(16.1)	9.0
Income (loss) from discontinued Operations (net of tax)	(15.6)	0.1
	-----	-----
Net income (loss)	(31.7)%	8.9%
	=====	=====

Note. Comparisons to the corresponding quarter of the prior year include adjustments to remove the operations of the discontinued segment.

Sales. Our sales decreased 29% to \$5.7 million for the three months ended March 31, 2001 from \$8.0 million for the three months ended April 1, 2000. In general, the decrease in our sales was due to decreased unit sales, primarily for the OcuLight SLx for ophthalmology and the DioLite for dermatology, as a result of weakening economic conditions in the United States. More specifically, sales of our ophthalmology OcuLight SLx infrared products decreased as a result of uncertainties surrounding Medicare reimbursement for certain AMD procedures using our products. In addition, key component supply difficulties delayed shipments of our DioLite and, to a lesser extent, our OcuLight GL and GLx laser systems. As a result of these shipment delays, the Company closed the quarter with an increased backlog for such products and related delivery devices of approximately \$500,000. The Company believes that sufficient quantities of the component will be available during the second quarter to satisfy both the first quarter

backlog and the second quarter production requirements. Domestic sales of \$3.1 million accounted for 54% of sales for the three months ended March 31, 2001 compared to \$5.3 million or 66% of sales in the comparable 2000 period. The decrease in domestic sales was widespread with decreases in ophthalmology and dermatology as specifically mentioned above. International sales of \$2.6 million accounted for 46% of sales for the three months ended March 31, 2001 compared to \$2.8 million or 34% in the comparable 2000 period. The slight decrease in international sales was primarily due to decreases in sales of the OcuLight SLx for ophthalmology and the DioLite for dermatology, offset in part by increases in sales of peripheral devices and disposable probes. International ophthalmology product sales decreases were primarily in Europe, offset in part by an increase in sales to the Asian region. We expect revenues from international sales to continue to account for a substantial portion of our sales. We expect near term growth in sales to be primarily derived from sales of the Apex 800 hair removal laser for dermatology, which we expect to begin shipping in the second quarter of 2001. The Company has been actively working with local Medicare carriers to resolve the reimbursement issues which have impacted sales of SLx and related delivery devices. We expect favorable resolution of these issues late in 2001. We expect a near term reduction of sales of the OcuLight SLx and related delivery devices as compared to prior year equivalent levels due to the ongoing reimbursement uncertainty.

Gross Profit. Our gross profit decreased 49% to \$2.4 million for the three months ended March 31, 2001 from \$4.7 million for the three months ended April 1, 2000. Gross profit as a percentage of net sales for the three months ended March 31, 2001 decreased to 41%, compared to 58% for the three months ended April 1, 2000, due primarily to the decreased sales volume of the OcuLight SLx and DioLite and the percentage decrease in domestic sales, all of which have higher gross profit margins. Domestic product sales have higher average sales prices, as they are transacted directly with the user-customer by a direct sales force, as compared to international product sales which are transacted through independent distributors. We expect to begin shipping the Apex 800 hair removal laser system in the second quarter of 2001. As a result, we expect the gross profit margin to drop slightly from the rate in the second quarter of 2000 since initial production costs for the Apex 800 are likely to cause a comparatively lower gross profit margin. We also expect our gross profit margins to continue to fluctuate due to changes in the relative proportions of domestic and international sales, mix of sales of existing products, pricing, product costs and a variety of other factors.

Research and Development. Our research and development expenses increased by 21% to \$1.3 million for the three months ended March 31, 2001 from \$1.1 million for the three months ended April 1, 2000. Research and development expenses increased as a percentage of net sales to 23% for the three months ended March 31, 2001 from 14% for the comparable prior year three-month period. The increase in research and development expenses in absolute dollars during this period was primarily attributable to increases in personnel, clinical study expenses and other resources as we increased our product and applications development efforts. We expect these expenses for research and development to continue to increase in absolute dollars during the remainder of 2001 in connection with activities related to new products, such as the Apex 800, and clinical treatment development, such as the Transpupillary Thermotherapy (TTT) for AMD study. Research and development expenses as a percentage of net sales increased during this period due to the decrease in revenue relative to the rate of growth of research and development expenses.

Sales, General and Administrative. Our sales, general and administrative expenses increased by 6% to \$2.8 million for the three months ended March 31, 2001 from \$2.7 million for the three months ended April 1, 2000. Sales, general and administrative expenses increased as a percentage of net sales to 49% for the three months ended March 31, 2001 from 33% for the comparable prior year three-month period. The increase in absolute dollars in sales, general and administrative expenses was primarily due to increased marketing efforts and the hiring of additional employees to support unit sales volumes for our medical products and administrative activities. We expect sales, general and administrative expenses to increase

slightly in absolute dollars during the balance of 2001 to support the level of expected shipments and employees. Sales, general and administrative expenses as a percentage of net sales increased during this period due to the decrease in revenue relative to the rate of growth of sales, general and administrative expenses. We expect sales, general and administrative expenses as a percentage of net sales to decrease during the balance of 2001 as revenues increase.

Income Taxes. For the three months ended March 31, 2001, the effective tax benefit rate from continuing operations was 42%. This rate differs from the federal statutory rate primarily due to state income taxes, offset by the utilization of tax credits, non-taxable available-for-sale security investments and tax benefits from our foreign sales corporation.

Discontinued Operations. In April 2001, management decided to discontinue the Laser Research segment. Revenues of this segment totalled \$25,000 and \$196,000 for the three months ended March 31, 2001 and April 1, 2000, respectively. Costs and operating expenses of this segment totalled \$918,000 and \$211,000 for the three months ended March 31, 2001 and April 1, 2000, respectively. The total loss on discontinued operations of \$893,000 (net of a \$542,000 income tax benefit) for the three months ended March 31, 2001 consisted primarily of inventory and sales return costs. No assets or liabilities of the Laser Research segment remain and no proceeds are expected from the disposition of this segment.

LIQUIDITY AND CAPITAL RESOURCES

At March 31, 2001, our primary sources of liquidity included cash and cash equivalents and available-for-sale securities in the aggregate amount of \$11.8 million. In addition, we have available \$2 million under our unsecured line of credit which bears interest at the bank's prime rate and expires in September 2001. As of March 31, 2001, no borrowings were outstanding under this credit facility.

During the three months ended March 31, 2001, we consumed \$2.5 million in cash and cash equivalents. During this period, operating activities consumed a net \$1.1 million of cash. Uses of cash included a net loss of \$1.8 million, a net increase in accounts payable and accrued expenses totalling \$1.2 million and a net increase in inventory of \$0.2 million, offset in part by sources of cash from operating activities which included a net decrease in accounts receivable of \$1.5 million, discontinued operations of \$0.6 million, and depreciation and amortization of \$0.2 million.

We consumed \$1.5 million in cash in investing activities during the three months ended March 31, 2001, primarily from the net purchases of \$1.3 million of available-for-sale securities and by the acquisition of \$0.2 million of property and equipment.

Net cash provided by financing activities during the three months ended March 31, 2001 was \$0.1 million which consisted of the issuance of common stock.

We believe that, based on current estimates, our cash and cash equivalents and available-for-sale securities together with cash generated from operations will be sufficient to meet our anticipated cash requirements for the next 12 months.

In December 1998, we instituted a stock repurchase program whereby up to 150,000 shares of our Common Stock may be repurchased in the open market. We plan to utilize all of the reacquired shares for reissuance in connection with employee stock programs. No shares were repurchased during the three months ending March 31, 2001. To date, we have purchased 76,000 shares of our Common Stock under this program.

FACTORS THAT MAY AFFECT FUTURE RESULTS

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

- ~ Product performance, procedures and price;
- ~ Opinions of medical advisors and associates;
- ~ Recommendations by ophthalmologists, dermatologists, clinicians, and their associated opinion leaders;
- ~ Performance of these laser systems and treatments which are a beneficial alternative to competing technologies and treatments;
- ~ The willingness of ophthalmologists and dermatologists to convert to semiconductor-based or infrared laser systems from visible argon gas or ion-based laser systems;
- ~ The level of reimbursement for treatments administered with our products; and
- ~ Our ability to introduce new products into these markets.

Any significant decline in market acceptance of our products would have a material adverse effect on our business, results of operations and financial condition. For example, we expect to introduce the Apex 800 in the second quarter of FY2001. Our stated expectations for future sales growth depends on market acceptance of this product. If the Apex 800 does not receive the level of market acceptance that we anticipate, our business, financial condition and results of operations could be materially and adversely effected.

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

academic and research institutions or others may develop new technologies or therapies that are more effective in treating conditions targeted by us or are less expensive than our current or future products. Any such developments could have a material adverse effect on our business, financial condition and results of operations.

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

We Depend on Sole Source Or Limited Source Suppliers. We rely on third parties to manufacture substantially all of the components used in our products, although we assemble critical subassemblies and the final product at our facility in Mountain View, California. Some of our suppliers are relatively small private companies that may discontinue their operations at any time. There are risks associated with the use of independent manufacturers, including unavailability of or delays in obtaining adequate supplies of components, including optics, laser diodes, and crystals and potentially reduced control of quality, production costs and timing of delivery. We may experience difficulty identifying alternative sources of supply for certain components used in our products. 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 a second source for this component during the first fiscal Quarter of 2001. The process of qualifying suppliers is ongoing and may be lengthy, particularly as new products are introduced. However, we have qualified two or more sources for most of the components used in our products. In addition, the use of alternate components may require design alterations which may delay installation and increase product costs. We have some long term or volume purchase agreements with our suppliers and currently purchase components on a purchase order basis. These components may not be available in the quantities required, on reasonable terms, or at all. Financial or other difficulties faced by our suppliers or significant changes in demand for these components or materials could limit their availability. Any failures by such third parties to adequately perform may delay the submission of products for regulatory approval, impair our ability to deliver products on a timely basis or otherwise impair our competitive position. Establishing our own capabilities to manufacture these components would be expensive and could significantly decrease our profit margins. Our business, results of operations and financial condition would be adversely affected if we were unable to continue to obtain components as required at a reasonable cost.

We Depend on International Sales. We derive and expect to continue to derive a large portion of our revenue from international sales. In 2000 and 1999, our international sales were \$11.7 million and \$10.2 million, or 35% and 38%, respectively, of total sales. For the three months ended March 31, 2001 and April 1, 2000, our international sales were \$2.6 million and \$2.8 million, representing 46% and 34%, respectively, of total sales. A large portion of our revenues will continue to be subject to the risks associated with international sales. These risks include currency fluctuations, shipping delays, generally longer

receivable collection periods, changes in applicable regulatory policies, domestic and foreign tax policies, trade restrictions, duties and tariffs and economic and political instability. In general, strengthening of the U.S. dollar relative to a foreign currency increases the cost of our product to our customers. Each of the factors stated above could have a material adverse effect on our ability to deliver products on a competitive and timely basis.

We Depend on Third Party Coverage and Reimbursement Policies. Our products are typically purchased by doctors, clinics, hospitals and other users, which bill various third-party payors, such as governmental programs and private insurance plans, for the health care services provided to their patients. Third-party payors carefully review and are increasingly challenging the prices charged for medical products and services. Reimbursement rates paid by third party payors may vary depending on the procedure performed, the third party payor, the insurance plan and other factors. Medicare reimburses hospitals on a prospectively determined fixed amount for the costs associated with an in-patient hospitalization based on the patient's discharge diagnosis. Medicare reimburses physicians a prospectively-determined fixed amount based on the procedure performed, regardless of the actual costs incurred by the hospital or physician in furnishing the care and regardless of the specific devices used in that procedure. Third-party payors are increasingly scrutinizing whether to cover new products and the level of reimbursement for covered products.

Doctors, clinics, hospitals and other users of our products may not obtain adequate reimbursement for use of our products from third-party payors. Payors may deny coverage and reimbursement for our products if they determine that the device was not reasonable and necessary for the purpose used, was investigational or was not cost-effective. For example, during July 2000, the Health Care Financing Administration (HCFA) advised that claims for reimbursement for certain AMD procedures that use our OcuLight SLx laser system would not be reimbursed by Medicare. In September 2000, HCFA changed its position and advised that claims for reimbursement for these AMD procedures can be submitted for reimbursement, with coverage and payment to be determined by the local Medicare carriers at their discretion. As a result, since July 2000, sales of the OcuLight SLx laser system have dropped significantly. Sales of the OcuLight SLx continue, albeit at a lower level, because the OcuLight SLx can also be used for other ophthalmic procedures with Medicare reimbursement. Furthermore, since HCFA policies apply only to third party Medicare payors, they are not likely to affect international sales. We believe domestic sales of the OcuLight SLx laser system will continue at these lower levels until more local Medicare carriers elect to cover and reimburse for performing such AMD procedures or until HCFA advises that claims for these procedures are Medicare covered and reimbursable. We believe that more Medicare carriers will reimburse for these procedures or HCFA will allow national standardized reimbursement for them when they are further validated by clinical studies. The Company is supporting a randomized clinical trial which may further validate Transpupillary Thermotherapy, the most significant of the subject AMD procedures.

We have developed a new laser system with Miravant, the OcuLight 664. Miravant may not be able to obtain coverage for its use of drugs with our OcuLight Systems, or the reimbursement may not be adequate to cover the treatment procedure.

Changes in government legislation or regulation or in private third-party payors' policies toward reimbursement for procedures employing our products may prohibit adequate reimbursement. Denial of coverage and reimbursement for our products could have a material adverse effect on our business, results of operations and financial condition. We are unable to predict what legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future, or what effect such legislation or regulation may have on us.

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

Our Operating Results Fluctuate from Quarter to Quarter. Our sales and operating results have varied substantially on a quarterly basis and may continue to vary in the future. Our operating results are affected by a number of factors, many of which are beyond our control. Factors contributing to these fluctuations include the following:

- ~ The timing of the introduction and market acceptance of new products, product enhancements and new applications, and their reimbursement;
- ~ The cost and availability of components and subassemblies;
- ~ Changes in our pricing and our competitors;
- ~ Our long and highly variable sales cycle;
- ~ Changes in customers' or potential customers' budgets; and
- ~ Increased product development costs.

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

Our expense levels are based, in part, on expected future sales. If sales levels in a particular quarter do not meet expectations, we may be unable to adjust operating expenses quickly enough to compensate for the shortfall of sales, and our results of operations may be adversely affected. In addition, we have historically made a significant portion of each quarter's product shipments near the end of the quarter. If that pattern continues, any delays in shipment of products could have a material adverse effect on results of operations for such quarter. As a result of the above factors, sales for any future quarter are not predictable with any significant degree of accuracy and operating results in any period should not be considered indicative of the results to be expected for any future period. There can be no assurance that we will remain profitable in the future or that operating results will not vary significantly.

We Depend on Development of New Products and New Applications. Our future success is dependent upon, among other factors, our ability to develop, obtain regulatory approval of, manufacture and market, new products, such as the Apex 800 hair removal laser system. 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 and general economic conditions affecting purchasing patterns. Any failure in our ability to successfully develop and introduce new products, such as the Apex 800, or enhanced versions of existing products, could have a material adverse effect on our business, operating results and financial condition. We are seeking to expand the market for our existing and new products by working with clinicians and third parties to identify new applications and procedures for our products. Failure to develop and achieve market acceptance of new applications or new products would have a material adverse effect on our business, results of operations and financial condition.

We Must Manage Growth. We have experienced, and may continue to experience growth in production, the number of employees, the scope of our business, our operating and financial systems and the geographic area of our operations. This growth has resulted in new and increased responsibilities for management personnel and our operating, inventory and financial systems. To effectively manage future growth, if any, we have been required to continue to implement and improve operational, financial and management information systems, procedures and controls. In 1998 we implemented an enterprise-wide management information system. We must also expand, train, motivate and manage our work force. Our personnel, systems, procedures and controls may not be adequate to support our existing and future operations. Any failure to implement and improve our operational, financial and management systems or to expand, train, motivate or manage employees could have a material adverse effect on our business, results of operations and financial condition.

We Depend on Collaborative Relationships. We have entered into collaborative relationships with academic medical centers and physicians in connection with the research and development and clinical testing of our products. We plan to collaborate with third parties to develop and commercialize existing and new products. We are working with Miravant, formerly known as PDT, Inc., a maker of photodynamic drugs to collaborate on a device that emits a laser beam to activate a photodynamic drug developed by Miravant for the treatment of wet AMD. This collaborative development effort may not continue or it may not result in the successful development and introduction of a photodynamic system and the amount and timing of resources to be devoted to these activities are not within our control. Additionally, our reliance on others for clinical development, manufacturing and distribution of our products may result in unforeseen problems. Further, our collaborative partners may develop or pursue alternative technologies either on their own or in collaboration with others. The failure of any current or future collaboration efforts could have a material adverse effect on our ability to introduce new products or applications and therefore could have a material adverse effect on our business, results of operations and financial condition.

We Rely on Patents and Proprietary Rights. Our success and ability to compete is dependent in part upon our proprietary information. We rely on a combination of patents, trade secrets, copyright and trademark laws, nondisclosure and other contractual agreements and technical measures to protect our intellectual property rights. We file patent applications to protect technology, inventions and improvements that are significant to the development of our business. We have been issued ten United States patents on the technologies related to our products and processes. Our patent applications may not issue as patents, any patents now or in the future may not offer any degree of protection, or our patents or patent applications may be challenged, invalidated or circumvented in the future. Moreover, our competitors, many of which have substantial resources and have made substantial investments in competing technologies, may seek to apply for and obtain patents that will prevent, limit or interfere with our ability to make, use or sell our products either in the United States or in international markets.

In addition to patents, we rely on trade secrets and proprietary know-how which we seek to protect, in part, through proprietary information agreements with employees, consultants and other parties. Our proprietary information agreements with our employees and consultants contain industry standard provisions requiring such individuals to assign to us without additional consideration any inventions conceived or reduced to practice by them while employed or retained by us, subject to customary exceptions. Proprietary information agreements with employees, consultants and others may be breached, and we may not have adequate remedies for any breach. Also our trade secrets may become known to or independently developed by competitors.

The laser and medical device industry is characterized by frequent litigation regarding patent and other intellectual property rights. Companies in the medical device industry have employed intellectual

property litigation to gain a competitive advantage. Numerous patents are held by others, including academic institutions and our competitors. Because patent applications are maintained in secrecy in the United States until patents are issued and are maintained in secrecy for a period of time outside the United States, we have not conducted any searches to determine whether our technology infringes any patents or patent applications. We have from time to time been notified of, or have otherwise been made aware of, claims that we may be infringing upon patents or other proprietary intellectual property owned by others. If it appears necessary or desirable, we may seek licenses under such patents or proprietary intellectual property. Although patent holders commonly offer such licenses, licenses under such patents or intellectual property may not be offered or the terms of any offered licenses may not be reasonable. This may adversely impact our operating results.

Any claims, with or without merit, could be time-consuming, result in costly litigation and diversion of technical and management personnel, cause shipment delays or require us to develop noninfringing technology or to enter into royalty or licensing agreements. Although patent and intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. An adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our products, which would have a material adverse effect on our business, results of operations and financial condition. Conversely, litigation may be necessary to enforce patents issued to us, to protect trade secrets or know-how owned by us or to determine the enforceability, scope and validity of the proprietary rights of others. Both the defense and prosecution of intellectual property suits or interference proceedings are costly and time consuming.

We Are Subject To Government Regulation. The medical devices that we market and manufacture are subject to extensive regulation by the FDA and by foreign and state governments. Under the FDA Act and the related regulations, the FDA regulates the design, development, clinical testing, manufacture, labeling, sale, distribution and promotion of medical devices. Before a new device can be introduced into the market, the manufacturer must obtain market clearance through either the 510(k) premarket notification process or the lengthier premarket approval ("PMA") application process. Obtaining these approvals can take a long time and delay the introduction of a product. For example, the introduction of the OcuLight GL in the United States was delayed about three months from our expectations due to the longer than expected time period required to obtain FDA premarket clearance. Noncompliance with applicable requirements, including Quality System Regulations ("QSRs"), can result in, among other things, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the government to grant premarket clearance or premarket approval for devices, withdrawal of marketing approvals, and criminal prosecution. The FDA also has the authority to request repair, replacement or refund of the cost of any device we manufacture or distribute. Our failure to obtain government approvals or any delays in receipt of such approvals would have a material adverse effect on our business, results of operations and financial condition.

International regulatory bodies often establish varying product standards, packaging requirements, labeling requirements, tariff regulations, duties and tax requirements. As a result of our sales in Europe, we are required to have all products "CE" registered, an international symbol affixed to all products demonstrating compliance to the European Medical Device Directive and all applicable standards. In July 1998, we received CE registration under Annex II guidelines, the most stringent path to CE registration. With Annex II CE registration, 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 IRIS Medical and IRIDERM products are CE registered. Continued registration is based on successful review of the process by our

European Registrar during their annual audit. Any loss of registration would have a material adverse effect on our business, results of operations and financial condition.

We Face Product Liability Risks. We may be subject to product liability claims in the future. Our products are highly complex and are used to treat extremely delicate eye tissue and skin conditions on and near a patient's face. Product defects or the improper use of our products could cause blindness, eyesight damage or skin damage. In addition, although we recommend that our disposable products only be used once and so prominently label these disposables, we believe that certain customers may nevertheless reuse these disposable products. Accordingly, the manufacture and sale of medical products entails significant risk of product liability claims. Although we maintain product liability insurance with coverage limits of \$11.0 million per occurrence and an annual aggregate maximum of \$12.0 million, our coverage from our insurance policies may not be adequate. Such insurance is expensive and in the future may not be available on acceptable terms, if at all. A successful claim brought against us in excess of our insurance coverage could have a material adverse effect on our business, results of operations and financial condition. To date, we have not experienced any product liability claims which would result in payments in excess of our policy limits.

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

QUANTITATIVE DISCLOSURES

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

Interest Rate Risk. We are subject to interest rate risks on cash and cash equivalents, available-for-sale marketable securities and any future financing requirements. Interest rate risks related to marketable securities are managed by managing maturities in our marketable securities portfolio. We have no long-term debt as of March 31, 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 2001 and the interest rates are primarily fixed.

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

	March 31, 2001 -----	Total -----	Fair value -----
Assets:			
Cash, cash equivalents.....	\$7,548	\$7,548	\$7,548
Weighted average interest rate	3.58%	--	--
Short-term marketable securities	\$4,256	\$4,256	\$4,256
Weighted average interest rate	4.74%	--	--

QUALITATIVE DISCLOSURES

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

~ The available-for-sale securities will fall in value if market interest rates increase.

~ The impact of interest rate movements on our ability to obtain adequate financing to fund future operations.

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

Management evaluates our financial position on an ongoing basis.

Currency Rate Risk

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

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. SUBMISSION OF MATTERS TO VOTE OF SECURITY HOLDERS

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

None

(b) Reports on Form 8-K

We filed a Current Report on Form 8-K on April 5, 2001 with the Securities and Exchange Commission to report the issuance of a press release announcing lower than expected earnings for our first quarter of 2001.

SIGNATURE

Pursuant to the requirements 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.

IRIDEX Corporation
(Registrant)

Date: May 15, 2001

By: /s/ Robert Kamenski

Robert Kamenski
Chief Financial Officer
(Principal Financial and
Principal Accounting Officer)