UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 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 [X] No [ ]; (2) Yes [X] No [ ]

The number of shares of Common Stock, $.01 par value, issued and outstanding as of August 6, 2001 was 6,753,126 .

IRIDEX CORPORATION

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IRIDEX CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS)

	JUNE 30, 2001	DECEMBER 30, 2000
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,756	$ 9,998
Available-for-sale securities	3,272	2,996
Accounts receivable, net	6,861	8,010
Inventories	10,451	9,721
Prepaids and other current assets	590	805
Total current assets	28,930	31,530
Property and equipment, net	1,782	1,903
Deferred income taxes	1,592	1,592
Total assets	$ 32,304	$ 35,025
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,570	$ 1,408
Accrued expenses	1,909	3,117
Total liabilities	3,479	4,525
Stockholders' equity:		
Common stock	68	67
Additional paid-in capital	22,823	22,691
Accumulated other comprehensive income	8	10
Retained earnings	5,926	7,732
Total stockholders' equity	28,825	30,500
Total liabilities and stockholders' equity	$ 32,304	$ 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 PER SHARE DATA)
(UNAUDITED)

	THREE MONTHS ENDED		SIX MONTHS ENDED	
	JUNE 30, 2001	JULY 1, 2000	JUNE 30, 2001	JULY 1, 2000
Sales	7,088	$ 8,785	$ 12,823	$ 16,781
Cost of sales	3,391	3,636	6,763	6,975
Gross Profit	3,697	5,149	6,060	9,806
Operating expenses:				
Research and development	1,176	1,362	2,488	2,580
Sales, general and administrative	2,624	2,828	5,422	5,505
Total operating expenses	3,800	4,190	7,910	8,085
Operating income (loss) from continuing operations	(103)	959	(1,850)	1,721
Other income, net	121	140	261	276
Income (loss) before benefit from (provision) for income taxes	18	1,099	(1,589)	1,997
Benefit from (provision) for income taxes	(7)	(352)	676	(639)
Income (loss) from continuing operations	11	747	(913)	1,358
Income (loss) from discontinued operations (net of applicable income tax benefit (provision) of $-, $15, $542 and $(32), respectively)	0	(31)	(893)	69
Net income (loss)	$ 11	$ 716	$ (1,806)	$ 1,427
Income (loss) from continuing operations per common share-basic	$ 0.00	$ 0.11	$ (0.14)	$ 0.21
Income (loss) from discontinued operations per common share-basic	0.00	0.00	(0.13)	0.01
Net income (loss) per common share-basic	$ 0.00	$ 0.11	$ (0.27)	$ 0.22
Income (loss) from continuing operations per common share-diluted	$ 0.00	$ 0.10	$ (0.14)	$ 0.18
Income (loss) from discontinued operations per common share-diluted	0.00	0.00	(0.13)	0.01
Net income (loss) per common share-diluted	$ 0.00	$ 0.10	$ (0.27)	$ 0.19
Shares used in per common share basic calculations	6,742	6,638	6,727	6,610
Shares used in per share-assuming dilution calculations	6,874	7,360	6,727	7,348

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

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

	SIX MONTHS ENDED	
	JUNE 30, 2001	JULY 1, 2000
Cash flows from operating activities:		
Net income (loss)	$ (1,806)	$ 1,427
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Discontinued operations	564	--
Depreciation and amortization	421	462
Provision for inventories	140	--
Provision for sales returns	--	100
Changes in operating assets and liabilities:		
Accounts receivable	1,141	(592)
Inventories	(1,544)	(1,070)
Prepaids and other current assets	212	(56)
Accounts payable	94	894
Accrued expenses	(991)	(595)
Net cash provided by (used in) operating activities	(1,769)	570
Cash flows from investing activities:		
Purchases of available-for-sale securities	(1,367)	(1,837)
Proceeds from maturity of available-for-sale securities	1,089	3,505
Acquisition of property and equipment	(328)	(443)
Net cash provided by (used in) investing activities	(606)	1,225
Cash flows from financing activities:		
Issuance of common stock, net	133	254
Net cash provided by financing activities	133	254
Net increase (decrease) in cash and cash equivalents	(2,242)	2,049
Cash and cash equivalents at beginning of period	9,998	9,645
Cash and cash equivalents at end of period	$ 7,756	$ 11,694
SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING ACTIVITIES:		
Change in unrealized (losses) on available-for-sale securities	$ (2)	$ --

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		SIX MONTHS ENDED	
	JUNE 30, 2001	JULY 1, 2000	JUNE 30, 2001	JULY 1, 2000
Net income (loss)	$ 11	$ 716	$(1,806)	$ 1,427
Other comprehensive income (loss):				
Change in unrealized gain (loss) on available-for-sale securities	(5)	1	(2)	--
Comprehensive income (loss)	$ 6	$ 717	$(1,808)	$ 1,427

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 in the United States of America 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 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 and six month periods ended June 30, 2001 are not necessarily indicative of the results for the year ending December 29, 2001 or any future interim period.

2. INVENTORIES COMPRISE (IN THOUSANDS):

	JUNE 30, 2001	DECEMBER 30, 2000
	(unaudited)	
Raw materials and work in progress	$ 6,077	$ 6,168
Finished goods	4,374	3,553
Total inventories	$10,451	$ 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 per common share and diluted net income per common share is as follows (in thousands, except per share amounts):

	THREE MONTHS ENDED		SIX MONTHS ENDED	
	JUNE 30, 2001	JULY 1, 2000	JUNE 30, 2001	JULY 1, 2000
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Numerator				
Income (loss) from continuing operations	$ 11	$ 747	$ (913)	$ 1,358
Income (loss) from discontinued operations	--	(31)	(893)	69
Net income (loss)	$ 11	$ 716	$(1,806)	$ 1,427
Denominator -- Basic				
Weighted average common stock outstanding	6,742	6,638	6,727	6,610
Basic income (loss) per share from continuing operations	$ 0.00	$ 0.11	$ (0.14)	$ 0.21
Basic income (loss) per share from discontinued operations	0.00	0.00	(0.13)	0.01
Basic income (loss) per share	$ 0.00	$ 0.11	$ (0.27)	$ 0.22
Denominator -- Diluted				
Weighted average common stock outstanding	6,742	6,638	6,727	6,610
Effect of dilutive securities				
Weighted average common stock options	132	722	--	738
Total weighted average stock and options outstanding	6,874	7,360	6,727	7,348
Diluted income (loss) per share from continuing operations	$ 0.00	$ 0.10	$ (0.14)	$ 0.18
Diluted income (loss) per share from discontinued operations	0.00	0.00	(0.13)	0.01
Diluted income (loss) per share	$ 0.00	$ 0.10	$ (0.27)	$ 0.19

During the three months ended June 30, 2001 and July 1, 2000, options to purchase 849,821 and 31,397 shares at weighted average exercise prices of $7.39 and $14.65 per share were outstanding, but were not included in the computations of diluted net income per common share because the exercise price of the related options exceeded the average market price of the common shares for the respective periods. For the six months ended June 30, 2001 and July 1, 2000 options to purchase 723,808 and 23,090 shares at weighted average exercise prices of $8.01 and $14.74 per share were outstanding but not included in the computations of diluted net income per common share because the exercise price of the related options exceeded the average market price of the common shares. These options could dilute earnings per share in future periods.

4. DISCONTINUED OPERATIONS

In April 2001, management decided to discontinue the Laser Research segment. There were no revenues for this segment for both the three month periods ended July 1, 2000 and June 30, 2001, respectively. Costs and operating expenses of this segment totaled $46,000 for the three months ended July 1, 2000. There were no costs or operating expenses for this segment for the three months ended June 30, 2001. The total loss on discontinued operations of $893,000 (net of a $542,000 income tax benefit) was recorded in the first quarter of 2001 and consisted primarily of inventory and sales returns 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 and six month periods ended July 1, 2000 was based on an estimated effective income tax rate of 32% for the fiscal year ended December 30, 2000. For the three and six month periods ended June 30, 2001, the effective tax rate for continuing operations was 40% and 42%, respectively.

6. 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 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, and 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.

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 the level of international sales, including the impact of the decline in the value of the Euro on international sales; future sales growth, including potential increased sales of our ophthalmology products and the Apex 800; resolution of Medicare 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 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 statement of operations for the periods indicated.

	THREE MONTHS ENDED		SIX MONTHS ENDED	
	JUNE 30, 2001	JULY 1, 2000	JUNE 30, 2001	JULY 1, 2000
Sales	100.0%	100.0%	100.0%	100.0%
Cost of sales	47.8	41.4	52.7	41.6
Gross profit	52.2	58.6	47.3	58.4
Operating expenses:				
Research and development	16.6	15.5	19.4	15.4
Sales, general and administrative	37.0	32.2	42.3	32.8
Total operating expenses	53.6	47.7	61.7	48.2
Operating income (loss) from continuing operations	(1.4)	10.9	(14.4)	10.2
Other income, net	1.7	1.6	2.0	1.7
Income (loss) from continuing operations before provision for income taxes	0.3	12.5	(12.4)	11.9
Benefit (provision) for income taxes	(0.1)	(4.0)	5.3	(3.8)
Income (loss) from continuing operations	0.2	8.5	(7.1)	8.1
Income (loss) from discontinued operations (net of tax)	0.0	(0.4)	(7.0)	0.4
Net income (loss)	0.2%	8.1%	(14.1)%	8.5%

Sales. Our sales decreased 19% to $7.1 million for the three months ended June 30, 2001 from $8.8 million for the three months ended July 1, 2000. Overall, the decrease in our sales was due to decreased unit sales, primarily for the ophthalmology OcuLight SLx infrared products, as a result of weakened economic conditions in the United States of America. More specifically, sales of our OcuLight SLx products decreased as a result of uncertainties surrounding Medicare reimbursement for certain AMD procedures using our products. Additionally, during the second quarter of 2000, the Company made sales of the OcuLight 664 in connection with studies evaluating the effectiveness of photodynamic therapy for the treatment of age related macular

degeneration (AMD). In the second quarter of 2001, we made no such sales. The decreased sales of ophthalmology products was offset, in part, by increased sales of dermatology products, primarily the DioLite 532. Part of the increase was due to shipments of orders received in the first quarter of 2001 that were delayed to the second quarter of 2001 due to a key component supply issue. The key component supply issue was resolved in the second quarter of 2001. In addition, orders for the DioLite 532 increased in the second quarter of 2001 compared to the corresponding 2000 quarter. Domestic sales of $4.0 million accounted for 57% of sales for the three months ended June 30, 2001, compared to $5.9 million, or 68% of sales in the comparable 2000 period. The decrease in domestic sales in absolute dollars was due to decreases in ophthalmology product sales offset, in part, by increases in dermatology product sales. International sales of $3.0 million accounted for 43% of sales for the three months ended June 30, 2001, compared to $2.8 million, or 32% of sales in the comparable 2000 period. The increase in international sales was primarily due to increases in dermatology product sales, offset by a slight decrease in ophthalmology sales. The overall increase in international sales occurred primarily in Europe. We expect revenues from international sales to continue to account for a substantial portion of our sales. We expect future growth in sales to be primarily derived from sales of ophthalmology products and related delivery devices, and the Apex 800 hair removal laser systems for dermatology. We commenced revenue shipments of the Apex 800 in the third quarter of 2001.

Gross Profit. Our gross profit decreased 28% to $3.7 million for the three months ended June 30, 2001 compared to $5.1 million for the three months ended July 1, 2000. Gross profit as a percentage of net sales for the three months ended June 30, 2001 decreased to 52.2%, compared to 58.6% for the three months ended July 1, 2000, primarily due to the decreased sales volume of the OcuLight SLx which has a relatively higher gross margin. In addition, a higher percentage of international product sales, which have lower average sales prices as they are transacted through independent distributors, had the impact of lowering our gross profit as a percentage of revenue. For the six months ended June 30, 2001, our gross profit decreased 38.2% to $6.1 million as compared to $9.8 million for the comparable period in 2000. Gross profit as a percentage of net sales for the six months ended June 30, 2001 decreased to 47.3%, compared to 58.4% for the six months ended July 1, 2000. The decrease in gross profit for the six months ended July 1, 2000 was due primarily to the decreased sales volume of the OcuLight SLx. For the balance of 2001, we expect manufacturing costs to increase in absolute dollars to support increasing unit shipment volumes of existing products. In addition, we commenced revenue shipments of the Apex 800 hair removal laser system in the third quarter of 2001. We expect the gross profit margin to drop slightly during the third quarter of 2001, as compared to the second quarter of 2001, due to higher initial production costs for the Apex 800. 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 decreased by 13.7% to $1.2 million for the three months ended June 30, 2001 from $1.4 million for the three months ended July 1, 2000. Research and development expenses increased as a percentage of net sales to 16.6% for the three months ended June 30, 2001 from 15.5% for the comparable prior year three-month period. For the six months ended June 30, 2001, research and development expenses decreased 3.6% to $2.5 million as compared to $2.6 million for the six months ended July 1, 2000. Research and development expenses as a percentage of net sales increased during the period to 19.4% for the six months ended June 30, 2001 from 15.4% for the comparable 2000 period. The decrease in research and development expense in absolute dollars for both the three and six month periods was due primarily to the completion of development work on the Apex 800 hair removal laser system during the second quarter of 2001. The increase as a percentage of sales for both the three and six month periods was driven primarily by the decrease in sales which exceeded the decrease in research and development expense. We expect expenses for research and development to increase in absolute dollars during the remainder of 2001 as compared to the second quarter of 2001 in connection with activities related to new products and clinical treatment development, such as the Transpupillary thermotherapy (TTT) for Age-related Macular Degeneration (AMD) study that commenced in March 2000.

Sales, General and Administrative. Our sales, general and administrative expenses decreased by 7.2% to $2.6 million for the three months ended June 30, 2001 from $2.8 million for the three months ended July 1, 2000. The decrease in absolute dollars was due primarily to decreased selling expenses related to lower sales levels.

Sales, general and administrative expenses increased as a percentage of net sales to 37.0% for the three months ended June 30, 2001 from 32.2% for the comparable prior year three-month period. For the six months ended June 30, 2001, sales, general and administrative expenses decreased by 1.5% to $5.4 million from $5.5 million for the comparable period in 2000. Sales, general and administrative expenses as a percentage of net sales increased during this period to 42.3% for the six months ended June 30, 2001 from 32.8% for the comparable period in 2000. The decrease in absolute dollars in sales, general and administrative expenses for both the three and six month periods is due primarily to the decrease in commissions related to decreased revenue. The increase as a percentage of net sales for both the three and six month periods is due to the decrease in revenue relative to the decrease in 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 compared to the second quarter of 2001, as revenues increase.

Discontinued Operations. In April 2001, management decided to discontinue the Laser Research segment. There were no revenues for this segment for either of the three month periods ended July 1, 2000 and June 30, 2001, respectively. Costs and operating expenses of this segment totaled $46,000 for the three months ended July 1, 2000. There were no costs or operating expenses for this segment for the three months ended June 30, 2001. The total loss on discontinued operations of $893,000 (net of a $542,000 income tax benefit) was recorded in the first quarter of 2001 and consisted primarily of inventory and sales returns 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 June 30, 2001, our primary sources of liquidity included cash and cash equivalents and available-for-sale securities in the aggregate amount of $11.0 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 June 30, 2001, no borrowings were outstanding under this credit facility.

During the six months ended June 30, 2001, we used $2.2 million in cash and cash equivalents. During this period, operating activities used $1.8 million of cash. Uses of cash from operating activities included a net loss of $1.8 million, a decrease in accounts payable and accrued expenses of an aggregate of $0.9 million and an increase in net inventories of $1.4 million, partially offset by sources of cash including a decrease in accounts receivable of $1.1 million, discontinued operations of $0.6 million, depreciation of $0.4 million and a decrease in prepaids and other current assets of $0.2 million.

We consumed $0.6 million in cash and cash equivalents with investing activities during the six months ended June 30, 2001, primarily due to the acquisition of $0.3 million of property and equipment and net purchases of $0.3 million of available-for-sale securities.

Net cash provided by financing activities during the six months ended June 30, 2001 was $0.1 million which consisted of the issuance of common stock.

We believe that, based on current estimates, our cash, cash equivalents and available-for-sale securities together with operating cash flows 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 six months ended June 30, 2001. To date, we have purchased 76,000 shares of our Common Stock under this program.

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 operation 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 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, and 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.

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 and infrared 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 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. We commenced revenue shipments of the Apex 800 hair removal laser system in the third quarter of fiscal 2001. 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 results of operations could be materially and adversely effected. See "--We Depend on Third Party Coverage and Reimbursement Policies" and "--We Depend on Development of New Products and New Applications."

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 Lumenis (formerly ESC Medical, combined with Coherent Medical), Nidek, Inc., Carl Zeiss, Inc., Quantel and Alcon International and our principal competitors in dermatology are Lumenis, Candela Corporation, Cynosure, Inc., Laserscope and HGM. Some competitors have substantially greater financial, engineering, product development, manufacturing, marketing and technical resources than we do. 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. 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 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 additional sources for this component during the first fiscal quarter of 2001. The key component supply shortage was resolved in the second quarter of 2001. The key component supply shortage was resolved in the second 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 six months ended June 30, 2001 and July 1, 2000, our international sales were $5.7 million and $5.6 million, representing 44% and 32%, respectively, of total sales. Therefore, a large portion of our revenues will continue to be subject to the risks associated with international sales. 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 impact future sales levels from the region. The factors stated above could have a material adverse effect on our business, financial condition or results of operations.

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 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, Medicare advised that claims for reimbursement for certain AMD procedures that use our OcuLight SLx laser system would not be reimbursed. In September 2000, Medicare 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 Medicare 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 Medicare advises that claims for these procedures are covered and reimbursable. We believe that more Medicare carriers will reimburse for these procedures or Medicare 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;
- 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. We implemented a new 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 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. 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 development and support of this new photodynamic system will require significant financial and other resources. 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 eleven 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 IRIDEX 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

For the three and six month periods ended June 30, 2001, there has been no material change to the disclosure made in the 2000 Form 10-K.

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: August 14, 2001

By: /s/ Robert Kamenski

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