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 July 1, 2000

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

For the Transition period from

to

Commission File Number: 0-27598

IRIDEX CORPORATION

(Exact name of registrant as specified in its charter)

Delaware
-----(State or other jurisdiction of incorporation or organization)

77-0210467

(I.R.S. employer identification 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 July 31, 2000 was 6,624,358.

IRIDEX CORPORATION

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IRIDEX CORPORATION CONDENSED CONSOLIDATED BALANCE SHEETS (IN THOUSANDS)

	2000 ′	JANUARY 1, 2000
	(unaudited)	
ASSETS		
Current assets: Cash and cash equivalents Available-for-sale securities Accounts receivable, net Inventories Prepaids and other current assets	8,326 493	\$ 9,645 3,503 8,162 7,256 437
Total current assets	31,002	29,003
Property and equipment, net	2,125 1,518	1,518
Total assets		
LIABILITIES AND STOCKHOLDERS' EQUITY Current liabilities:		
Accounts payable	\$ 2,022 3,438	\$ 1,128 4,033
Total liabilities	5,460	5,161
Stockholders' equity: Common stock	67 22,377 (2) 6,743	66
Total stockholders' equity	29,185	27,504
Total liabilities and stockholders' equity	\$ 34,645 ======	\$ 32,665 ======

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

	THREE MONTHS	S ENDED	SIX MONTHS	ENDED
	JULY 1,	JULY 3,	JULY 1,	JULY 3,
	2000	1999	2000	1999
Sales Cost of sales		\$ 6,463 2,911	\$ 16,977 7,064	\$ 12,160 5,527
Gross Profit		3,552	9,913	6,633
Operating expenses: Research and development	2,828	874 2,333 3,207	2,586 5,505 8,091	1,842 4,334 6,176
Income from operations	913	345	1,822	457
	140	133	276	294
Income before provision for income taxes		478	2,098	751
Provision for income taxes	(337)	(153)	(671)	(241)
Net income	\$ 716	\$ 325	\$ 1,427	\$ 510
	======	======	======	======
Basic net income per common share	\$ 0.11	\$ 0.05	\$ 0.22 ======	\$ 0.08
Diluted net income per common share	\$ 0.10	\$ 0.05	\$ 0.19	\$ 0.08
	=====	=====	=====	=====
Shares used in basic net income per common share calculation	6,638	6,494	6,610	6,500
	======	=====	======	=====
common share calculation	7,360	6,744	7,348	6,756
	=====	======	======	======

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

	SIX MONT JULY 1, 2000	JULY 3,
Cash flows from operating activities: Net income	\$ 1,427	\$ 510
Depreciation and amortization	462 100	365
Accounts receivable	(592) (1,070) (56) 894 (595)	
Net cash provided by operating activities		1,564
Cash flows from investing activities: Purchases of available-for-sale securities Proceeds from maturity of available-for-sale securities Acquisition of intangible assets Acquisition of property and equipment	3,505 	(967) 2,778 (12) (284)
Net cash provided by investing activities	1,225	1,515
Cash flows from financing activities: Issuance of common stock, net Purchase of treasury stock		99 (232)
Net cash provided by (used in) financing activities		(133)
Net increase in cash and cash equivalents		
Cash and cash equivalents at beginning of period	9,645	5,791
Cash and cash equivalents at end of period	\$ 11,694 ======	\$ 8,737 ======
SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING ACTIVITIES: Change in unrealized losses on		
available-for-sale securities	\$	\$ (14)

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

	THREE MONTHS ENDED			SIX MONTHS ENDED			NDED				
	JU	JULY 1, JULY 3,		LY 3,	JULY 1,		JU	LY 3,			
	2	2000		2000 1999		999	2000		1	1999	
					-						
Net income Other comprehensive income (loss): Change in unrealized gain (loss) on	\$	716	\$	325	\$	1,427	\$	510			
available-for-sale securities		1		(8)				(14)			
					-						
Comprehensive income	\$ ==	717	\$	317 ====	\$	1,427	\$	496 ====			

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 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 31, 2000. The results of operations for the three month and six month periods ended July 1, 2000 are not necessarily indicative of the results for the year ending December 30, 2000 or any future interim period.

2. INVENTORIES COMPRISE (IN THOUSANDS):

	JULY 1, 2000	JANUARY 1 2000
	(unaudited)	
Raw materials and work in progress	,	\$ 3,839 3,417
Total inventories	\$ 8,326 ======	\$ 7,256 ======

3. COMPUTATIONS OF NET INCOME PER COMMON SHARE AND DILUTED NET INCOME PER COMMON SHARE

Net income per common share is computed using the weighted average number of shares of common stock outstanding during the period. Diluted net income per common share is computed using the weighted average number of shares of common stock and dilutive common equivalent shares from stock options outstanding.

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 JULY 1, JULY 3, 2000 1999		SIX MONTI JULY 1, 2000	_
		(unaudited)		(unaudited)
NumeratorNet income per common share and diluted net income per common share				
Net income DenominatorNet income per common share	\$ 716	\$ 325	\$ 1,427	\$ 510
Weighted average common stock outstanding	6,638	6,494	6,610	6,500
Basic net income per common share	\$ 0.11	\$ 0.05	\$ 0.22	\$ 0.08
	======	======	======	======
DenominatorDiluted net income per common share				
Weighted average common stock outstanding Effect of dilutive securities	6,638	6,494	6,610	6,500
Weighted average common stock options	722	250	738	256
Total weighted average stock and options				
outstanding	7,360 =====	6,744 =====	7,348 ======	6,756 =====
Diluted net income per common share	\$ 0.10 =====	\$ 0.05 =====	\$ 0.19 =====	\$ 0.08 =====



During the three and six months ended July 1, 2000 and July 3, 1999, options to purchase 31,397 and 306,462 shares at weighted average exercise prices of \$14.65 and \$7.56 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. These options could dilute earnings per share in future periods.

4. BUSINESS SEGMENTS (UNAUDITED)

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

Information on reportable segments for the three and six months ended July 1, 2000 and July 3, 1999 is as follows (in thousands):

	THREE MONTHS EMDED JULY 1, 2000		THREE MONTHS ENDED JULY 3, 1999		SIX MONTI JULY :	HS ENDED 1, 2000	SIX MONTHS ENDED JULY 3, 1999			
	Laser Medical Devices	Laser Research	Laser Medical Devices	Laser Research	Laser Medical Devices	Laser Research	Laser Medical Devices	Laser Research		
Sales	\$ 8,785	\$ 0	\$ 6,266	\$ 197	\$ 16,781	\$ 196	\$ 11,786	\$ 374		
Depreciation	198	3	180	4	456	6	352	8		
Income before provision for income taxes	1,099	(46)	403	75	1,996	101	556	195		

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

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 periods ended July 1, 2000 and July 3, 1999 are based on the estimated effective income tax rate of 32% for the fiscal years ending December 30, 2000 and January 1, 2000.

6. RECENT ACCOUNTING PRONOUNCEMENTS

In June 1998, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 133, or SFAS 133, "Accounting for Derivative Instruments and Hedging Activities." SFAS 133 will be effective for fiscal quarters beginning after June 15, 1999. In July of 1999, the FASB issued Statement of Financial Standards No. 137, Accounting for Derivative Instruments and Hedging Activities - Deferral of the Effective Date of FASB Statement No. 133 ("SFAS 137") which defers the effective date to all fiscal quarters of fiscal years beginning after June 15, 2000. The Company believes that SFAS 133 and 137 will not have a material effect on the financial position or results of operation of the Company. The Company does not currently hold derivative instruments or engage in hedging activities.

In December 1999, the Securities and Exchange Commission ("SEC") issued Staff Accounting Bulletin No. 101 (SAB 101), "Revenue Recognition in Financial Statements." SAB 101 provides guidance for revenue recognition under certain circumstances. The accounting and disclosures prescribed by SAB 101, as amended, will be effective for the fiscal year ended December 30, 2000. The Company is currently evaluating the impact of SAB 101 on its financial statements and related disclosures and does not expect any material impact from its application.

In March 2000, the FASB issued Interpretation No. 44, "Accounting for Certain Transactions Involving Stock Compensation - an interpretation of APB Opinion No. 25" ("FIN44"). This Interpretation clarifies the definition of an employee for the purposes of applying Accounting Practice Board Opinion No. 25, "Accounting for Stock Issued to Employees", the criteria for determining whether a plan qualifies as a noncompensatory plan, the accounting consequences of various modifications to the terms of a previously fixed stock option or award, and the accounting for an exchange of stock compensation awards in a business combination. This Interpretation is effective July 1, 2000, but certain conclusions in this Interpretation cover specific events that occur after either December 15, 1998, or January 12, 2000. The Company believes that FIN 44 will not have a material effect on its financial position or results of operation.

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

The discussion in Management's Discussion and Analysis of Financial Condition and Results of Operations contains trend analysis and other forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Actual results could differ materially from those set forth in such forward-looking statements as a result of the factors set forth under "Factors That May Affect Future 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 income statement for the periods indicated.

	THREE MON	NTHS ENDED	SIX MONTHS ENDED			
	JULY 1, 2000	JULY 3, 1999	JULY 1, 2000	JULY 3, 1999		
Sales	100.0%	100.0%	100.0%	100.0%		
Cost of sales	41.9	45.0	41.6	45.5		
Gross profit	58.1	55.0	58.4	54.5		
Operating expenses:						
Research and development	15.5	13.5	15.2	15.2		
Sales, general and administrative	32.2	36.1	32.4	35.6		
Total operating expenses	47.7	49.6	47.6	50.8		
<pre>Income (loss) from operations</pre>	10.4	5.4	10.7	3.7		
Other income, net	1.6	2.0	1.6	2.5		
Income before provision for income taxes	12.0	 7.4	12.4	6.2		
Provision for income taxes	(3.8)	(2.4)	(4.0)	(2.0)		
Net income	8.2% =====	5.0% =====	8.4% =====	4.2%		

Sales. Our sales increased 36% to \$8.8 million for the three months ended July 1, 2000 from \$6.5 million for the three months ended July 3, 1999. Sales increased 40% to \$17.0 million for the six months ended July 1, 2000 from \$12.2 million for the six months ended July 3, 1999. The increase was due primarily to strong sales of the Company's ophthalmology products, particularly increased sales of products used to treat Age-related Macular Degeneration (AMD). Sales of the Company's dermatology products were lower in the second quarter compared to sales for the corresponding 1999 quarter. This was due primarily to increased efforts to launch the new Apex 800 hair removal system which negatively impacted sales efforts for the DioLite 532, which is used in the treatment of vascular and pigmented lesions. During the quarter, the Company refocused on the DioLite 532 and expects sales levels of the DioLite 532 to improve. Domestic sales of \$5.9 million accounted for 67% of sales for the three months ended July 1, 2000 compared to \$3.7 million or 57% of sales in the comparable 1999 period. The increase in domestic sales was due to increases in ophthalmology product sales, offset in part by decreases in dermatology product sales. International sales of \$2.84 million accounted for 32% of sales for the three months ended July 1, 2000 compared to \$2.78 million or 43% in the comparable 1999 period. The increase in international sales was primarily due to increases in ophthalmology product sales, offset in part by decreases in dermatology product sales. International sales increases were primarily in Asia, Africa, the Americas and the Middle East, offset in part by a decrease in sales to 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 opthalmology products and related delivery devices, and the Apex 800 hair removal laser for dermatology. Introduction of the Apex 800, originally expected in the summer of 2000, has been delayed to the fall of 2000 due to a key component delay. As a result, no revenues for the Apex 800 are expected in the third quarter of 2000. These statements are forward looking statements. See "Factors that May Affect Future Performance" for a discussion of factors that may cause actual results to differ from those anticipated.

There were no sales into the research segment for the three months ended July 1, 2000 as compared with \$0.2 million for the three months ended July 3, 1999. For the six months ended July 1, 2000 sales were \$0.2 million as compared with \$0.4 million for the six months ended July 3, 1999.

Gross Profit. Our gross profit increased 44% to \$5.1 million for the three months ended July 1, 2000 from \$3.6 million for the three months ended July 3, 1999. Gross profit as a percentage of net sales for the three months ended July 1, 2000 increased to 58.1%, compared to 55% for the three months ended July 3, 1999, primarily due to the increased sales volume of the OcuLight SLx and increased domestic sales, both 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. For the six months ended July 1, 2000, our gross profit increased 58.4% to \$9.9 million as compared to \$6.6 million for the comparable period in 1999. For the balance of 2000, we expect manufacturing costs to increase in absolute dollars to support increasing unit shipment volumes. We expect to begin shipping the Apex 800 hair removal laser system in the fall of 2000. As a result, we expect the gross profit margin to drop slightly 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 56% to \$1.4 million for the three months ended July 1, 2000 from \$0.9 million for the three months ended July 3, 1999. Research and development expenses increased as a percentage of net sales to 15.5% for the three months ended July 1, 2000 from 13.5% for the comparable prior year three-month period. The increase in research and development expenses during this period was primarily attributable to increases in personnel, clinical study expenses and other resources as a result of an increase in development efforts for our applications and products, including the Apex 800 hair removal system. For the six months ended July 1, 2000, research and development expenses increased 40% to \$2.6 million as compared to \$1.8 million for the six months ended July 3, 1999. We expect these expenses for research and development to continue to increase in absolute dollars during the remainder of 2000 in connection with activities related to new products, such as the Apex 800, 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 increased by 21% to \$2.8 million for the three months ended July 1, 2000 from \$2.3 million for the three months ended July 3, 1999. Sales, general and administrative expenses decreased as a percentage of net sales to 32.2% for the three months ended July 1, 2000 from 36.1% 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 expanding unit sales volumes for our medical products and administrative activities. For the six months ended July 1, 2000, sales, general and administrative expenses increased by 27% to \$5.5 million from \$4.3 million for the comparable period in 1999. Sales, general and administrative expenses as a percentage of net sales decreased during this period due to the increase in the rate of growth of revenue relative to the rate of growth of sales, general and administrative expenses. We expect sales,

general and administrative expenses to continue to increase in absolute dollars during the balance of 2000 to support the increasing unit shipment volumes and additional employees.

Income Taxes. Our effective tax rate for the three months ended July 1, 2000 was 32%. This rate differs from the federal statutory rate primarily due to state income taxes, offset by the utilization of tax credits, non-taxable earnings on available-for-sale security investments and tax benefits from our foreign sales corporation.

LIQUIDITY AND CAPITAL RESOURCES

At July 1, 2000, our primary sources of liquidity included cash and cash equivalents and available-for-sale securities in the aggregate amount of \$13.5 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 2000. As of July 1, 2000, no borrowings were outstanding under this credit facility.

During the six months ended July 1, 2000, we generated \$2.0 million in cash and cash equivalents. During this period, operating activities provided \$0.6 million of cash. Sources of cash from operating activities included net income of \$1.4 million, depreciation and amortization of \$0.5 million, a net increase in accounts payable and accrued expenses of an aggregate of \$0.3 million, offset by uses of cash including an increase in inventories of \$1.1 million and an increase in accounts receivable of \$0.6 million. The increase in inventory was primarily due to an increase in raw materials inventory.

We generated \$1.2 million in investing activities during the six months ended July 1, 2000, primarily from the net maturities of \$1.7 million of available-for-sale securities offset by the acquisition of \$0.4 million of property and equipment.

Net cash provided by financing activities during the three months ended July 1, 2000 was \$0.3 million which consisted of the issuance of common stock.

We believe that, based on current estimates, our 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 six months ended July 1, 2000. To date, we have purchased 76,000 shares of our Common Stock under this program.

YEAR 2000 ISSUES

The Year 2000 computer problem refers to the potential for system and processing failures of date-related data as a result of computer controlled systems using two digits rather than four digits to define the applicable year. Prior to January 1, 2000, there was a great deal of concern regarding the ability of computers to adequately recognize 21st century dates from 20th century dates due to the two-digit fields used by many systems. Most reports to date, however, are that the computer systems are functioning normally and the compliance and

remediation work accomplished leading up to 2000 was effective in preventing any problems. Computer experts have warned that there may still be residual consequences of the change in centuries. If not corrected, these residual problems could result in miscalculations, data corruption, system failures or disruptions in operations during or beyond the year 2000. Any such difficulties could result in a decrease in sales of our products, an increase in allocation of resources to address Year 2000 problems of our customers without additional revenue commensurate with such dedication of resources, or an increase in litigation costs relating to losses suffered by our customers due to such Year 2000 problems.

Because our products are used in connection with components and systems designed and manufactured by others, residual Year 2000 problems affecting these components and systems could cause our products to fail. If residual Year 2000 problems cause the failure of any of the technology, software or systems used with our products, we could lose customers, suffer disruptions in our business, lose revenues and incur substantial liabilities and expenses. We could also become involved in costly litigation resulting from residual Year 2000 problems. Any of these occurrences could materially harm our business, financial condition or results of operations.

To date, we have not experienced, and do not expect to experience in the future, any Year 2000 issues with any of our internal systems or our products, or with any of our key third party suppliers, vendors, customers or service providers. The costs associated with remediating our internal systems have not been material to date.

RECENT ACCOUNTING PRONOUNCEMENTS

In June 1998, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 133, or SFAS 133, "Accounting for Derivative Instruments and Hedging Activities." SFAS 133 will be effective for fiscal quarters beginning after June 15, 1999. In July of 1999, the FASB issued Statement of Financial Standards No. 137, "Accounting for Derivative Instruments and Hedging Activities - Deferral of the Effective Date of FASB Statement No. 133" ("SFAS 137") which defers the effective date to all fiscal quarters of fiscal years beginning after June 15, 2000. The Company believes that SFAS 133 and 137 will not have a material effect on the financial position or results of operation of the Company. The Company does not currently hold derivative instruments or engage in hedging activities.

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In March 2000, the FASB issued Interpretation No. 44, "Accounting for Certain Transactions Involving Stock Compensation - an interpretation of APB Opinion No. 25" ("FIN44"). This Interpretation clarifies the definition of an employee for the purposes of applying Accounting Practice Board Opinion No. 25, "Accounting for Stock Issued to Employees", the criteria for determining whether a plan qualifies as a noncompensatory plan, the accounting consequences of various modifications to the terms of a previously fixed stock option or award, and the accounting for an exchange of stock compensation awards in a business combination. This Interpretation is effective July 1, 2000, but certain conclusions in this Interpretation cover specific events that occur after either December 15, 1998, or January 12, 2000. The Company believes that FIN 44 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 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:

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

For example, the Health Care Financing Administration (HCFA) of the Department of Health and Human Services has advised that claims for reimbursement for certain AMD procedures, including Transpupillary Thermotherapy (TTT), may not be reimbursed by Medicare. As a result, sales of our OcuLight SLx may decrease, which would affect our results of operations. The HCFA memorandum will not affect international sales. Any significant decline in market acceptance of our products would have a material adverse effect on our business, results of operations and financial condition.

Our Market is Competitive. Competition in the market for devices used for ophthalmic and 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, and HGM Medical Laser Systems, Inc. ("HGM") and our principal competitors in dermatology are Laserscope and HGM. Our newest product, 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. 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 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 Key Manufacturers and 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. There are risks associated with the use of independent manufacturers, including unavailability of or delays in obtaining adequate supplies of optics and laser diodes. We have qualified two or more sources for most of the components used in our products. In the past, we experienced delays in our manufacturing the OcuLight GL due to the inability of a supplier to deliver components in volume and on a timely basis. We have qualified a second source for this diode component. The process of qualifying suppliers is ongoing and may be lengthy, particularly as new products are introduced. We do not have long-term or volume purchase agreements with any of 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. 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 1999 and 1998, our international sales were \$10.3 million and \$8.6 million, or 39% and 37%, respectively, of total sales. For the three months ended July 1, 2000 and July 1, 1999, our international sales were \$2.84 million and \$2.78 million, representing 32% and 43%, respectively, of total sales. Therefore, a large portion of our revenues will continue to be subject to the risks associated with international sales. Economic difficulties in Asia and the devaluation of the currencies of many Asian countries in the past couple of years have significantly increased the purchase price of our products to our distributors in that region. Product sales were lower for the affected Asian region on a quarterly basis during 1998, and to a lesser extent during 1999 and the first quarter of 2000, as a result of the economic downturn and currency problem. The factors stated above could have a material adverse effect on our business, financial condition or results of operations.

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:

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

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 have implemented a new 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. In May 1996, we executed an agreement 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. 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 eight 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 March 2000, we entered into a patent license agreement with Palomar Medical Technologies, Inc. (PMTI). This agreement gives us a non-exclusive 7.5% royalty bearing sublicense to skin cooling patents for use in laser hair removal. The license provides the Apex 800 hair removal system with additional cooling features.

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.

We Face Risks of the Year 2000 Issue. Residual Year 2000 issues may disrupt our operations, subject us to liabilities and costs and affect the timing of our revenues. Prior to January 1, 2000, there was a great deal of concern regarding the ability of computers to adequately recognize 21st century dates from 20th century dates due to the two-digit fields used by many systems. Most reports to date, however, are that the computer systems are functioning normally and the compliance and remediation work accomplished leading to 2000 was effective in preventing any problems. Computer experts have warned that there may still be residual consequences of the change in centuries. If not corrected, these residual problems could result in miscalculations, data corruption, system failures or disruptions in operations during or beyond the year 2000. Any such difficulties could result in a decrease in sales of our products, an increase in allocation of resources to address Year 2000 problems of our customers without additional revenue commensurate with such dedication of resources, or an increase in litigation costs relating to losses suffered by our customers due to such Year 2000 problems.

Because our products are used in connection with components and systems designed and manufactured by others, residual Year 2000 problems affecting these components and sytems could cause our products to fail. If residual Year 2000 problems cause the failure of any of the technology, software or systems used with our products, we could lose customers, suffer disruptions in our business, lose revenues and incur substantial liabilities and expenses. We could also become involved in costly litigation resulting from Year 2000 problems. Any of these occurrences could materially harm our business, financial condition or results of operations.

To date, we have not experienced, and do not expect to experience in the future, any Year 2000 issues with any of our internal systems or our products, or with any of our key third party suppliers, vendors, customers or service providers. The costs associated with remediating our internal systems have not been material to date.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. We do not use derivative financial instruments in our investment portfolio and had no holdings of derivative financial or commodity instruments at July 1, 2000. A review of our financial instruments in our investment portfolio and risk exposures at that date revealed that we had exposure to interest rate risk. At July 1, 2000, we performed sensitivity analyses to assess the potential effect of this risk and concluded that near-term changes in interest rates should not materially adversely affect our financial position, results of operations 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 $8\mbox{-}\mbox{K}$

- (a) Exhibits
 - 27.1 Financial Data Schedule
- (b) Reports on Form 8-K

 $\,$ No reports on Form 8-K have been filed during the period for which this report is filed.

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 15, 2000 By: /s/ Robert Kamenski

Robert Kamenski Chief Financial Officer (Principal Financial and Principal Accounting Officer) 22

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27.1 Financial Data Schedule ____

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3-MOS
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             JUL-01-2000
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