

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended July 3, 1999

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

For the Transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 0-27598

IRIDEX CORPORATION

(Exact name of registrant as specified in its charter)

Delaware

77-0210467

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

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

(1) Yes  No ; (2) Yes  No

The number of shares of Common Stock, \$.01 par value, issued and outstanding as of August 12, 1999 was 6,468,346.

## IRIDEX CORPORATION

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IRIDEX CORPORATION  
 CONDENSED CONSOLIDATED BALANCE SHEETS  
 (IN THOUSANDS, EXCEPT SHARE DATA)  
 (UNAUDITED)

	JULY 3, 1999	JANUARY 2, 1999
	-----	-----
ASSETS		
Current assets:		
Cash and cash equivalents .....	\$ 8,737	\$ 5,791
Available-for-sale securities .....	3,260	5,085
Accounts receivable, net .....	6,760	7,608
Inventories .....	7,343	6,504
Prepays and other current assets .....	332	347
Deferred income taxes .....	607	607
	-----	-----
Total current assets .....	27,039	25,942
Property and equipment, net .....	2,198	2,274
Intangible assets .....	103	96
Deferred income taxes .....	65	65
	-----	-----
Total assets .....	\$ 29,405	\$ 28,377
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable .....	\$ 602	\$ 879
Accrued expenses .....	2,555	1,613
	-----	-----
Total liabilities .....	3,157	2,492
	-----	-----
Stockholders' equity:		
Common stock .....	66	65
Additional paid-in capital .....	21,898	21,800
Treasury stock .....	(232)	--
Accumulated other comprehensive income (loss) .....	(7)	7
Retained earnings .....	4,523	4,013
	-----	-----
Total stockholders' equity .....	26,248	25,885
	-----	-----
Total liabilities and stockholders' equity .....	\$ 29,405	\$ 28,377
	=====	=====

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

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

	THREE MONTHS ENDED		SIX MONTHS ENDED	
	JULY 3, 1999	JULY 4, 1998	JULY 3, 1999	JULY 4, 1998
Sales .....	\$ 6,463	\$ 6,002	\$ 12,160	\$ 11,874
Cost of sales .....	2,911	2,487	5,527	4,977
Gross Profit .....	3,552	3,515	6,633	6,897
Operating expenses:				
Research and development .....	874	677	1,842	1,223
Selling, general and administrative .....	2,333	2,160	4,334	4,135
Total operating expenses .....	3,207	2,837	6,176	5,358
Income from operations .....	345	678	457	1,539
Interest and other income (expense), net .....	133	117	294	248
Income before provision for income taxes ...	478	795	751	1,787
Provision for income taxes .....	(153)	(270)	(241)	(607)
Net income .....	\$ 325	\$ 525	\$ 510	\$ 1,180
Net income per common share .....	\$ 0.05	\$ 0.08	\$ 0.08	\$ 0.18
Diluted net income per common share .....	\$ 0.05	\$ 0.08	\$ 0.08	\$ 0.17
Shares used in per common share calculation .....	6,494	6,469	6,500	6,464
Shares used in diluted net income per common share calculation .....	6,744	6,855	6,756	6,834

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	
	JULY 3, 1999	JULY 4, 1998
Cash flows from operating activities:		
Net income .....	\$ 510	\$ 1,180
Adjustments to reconcile net income to net cash provided by (used in) activities:		
Depreciation and amortization .....	365	329
Provision for doubtful accounts .....	--	(20)
Changes in operating assets and liabilities:		
Accounts receivable .....	848	(1,396)
Inventories .....	(839)	(2,120)
Prepays and other current assets .....	15	37
Accounts payable .....	(277)	83
Accrued expenses .....	942	(147)
Net cash provided by (used in) operating activities .....	1,564	(2,054)
Cash flows from investing activities:		
Purchases of available-for-sale securities .....	(967)	(16,077)
Proceeds from maturity of available-for-sale securities .....	2,778	14,440
Acquisition of intangible assets .....	(12)	(44)
Acquisition of property and equipment .....	(284)	(472)
Net cash provided by (used in) investing activities .....	1,515	(2,153)
Cash flows from financing activities:		
Payment on capital lease obligations .....	--	(1)
Issuance of common stock, net .....	99	102
Purchase of treasury stock .....	(232)	--
Net cash (used in) provided by financing activities .....	(133)	101
Net increase (decrease) in cash and cash equivalents .....	2,946	(4,106)
Cash and cash equivalents at beginning of period .....	5,791	9,900
Cash and cash equivalents at end of period .....	\$ 8,737	\$ 5,794

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

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

	THREE MONTHS ENDED		SIX MONTHS ENDED	
	JULY 3, 1999	JULY 4, 1998	JULY 3, 1999	JULY 4, 1998
Net income .....	\$ 325	\$ 525	\$ 510	\$ 1,180
Other comprehensive income (loss):				
Changes in unrealized gain (loss) on available-for-sale securities .....	(8)	1	(14)	(1)
Comprehensive income .....	\$ 317	\$ 526	\$ 496	\$ 1,179

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 as of July 3, 1999 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 April 1, 1999. The results of operations for the three month and six month periods ended July 3, 1999 are not necessarily indicative of the results for the year ending January 1, 2000 or any future interim period.

2. RECLASSIFICATIONS

Certain prior year amounts have been reclassified to conform to the current year presentation. The reclassification had no impact on previously reported income from operations or net income.

3. INVENTORIES COMPRISE: (IN THOUSANDS)

	JULY 3, 1999	JANUARY 2, 1999	
	-----	-----	
	(unaudited)		
Raw materials and work in progress .....	\$ 4,336	\$ 3,877	
Finished goods .....	3,007	2,627	
	-----	-----	
Total inventories .....	\$ 7,343	\$ 6,504	
	=====	=====	

4. 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. 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		SIX MONTHS ENDED	
	JULY 3, 1999	JULY 4, 1998	JULY 3, 1999	JULY 4, 1998
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Numerator -- Net income per common share and diluted net income per common share				
Net income .....	\$ 325	\$ 525	\$ 510	\$ 1,180
Denominator -- Net income per common share				
Weighted average common stock outstanding .....	6,494	6,469	6,500	6,464
Net income per common share .....	\$ 0.05	\$ 0.08	\$ 0.08	\$ 0.18
Denominator -- Diluted net income per common share				
Weighted average common stock outstanding .....	6,494	6,469	6,500	6,464
Effect of dilutive securities				
Weighted average common stock options .....	250	386	256	370
Total weighted average stock and options outstanding .....	6,744	6,855	6,756	6,834
Diluted net income per common share .....	\$ 0.05	\$ 0.08	\$ 0.08	\$ 0.17

During the three months ended July 3, 1999 and July 4, 1998, options to purchase 306,462 and 137,168 shares, respectively, at weighted average exercise prices of \$7.56 and \$9.95 per share, respectively, 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.



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 MONTHS ENDED		SIX MONTHS ENDED	
	JULY 3, 1999	JULY 4, 1998	JULY 3, 1999	JULY 4, 1998
Sales .....	100.0%	100.0%	100.0%	100.0%
Cost of sales .....	45.0	41.4	45.5	41.9
Gross profit .....	55.0	58.6	54.5	58.1
Operating expenses:				
Research and development .....	13.5	11.3	15.2	10.3
Sales, general and administrative .....	36.1	36.0	35.6	34.8
Total operating expenses .....	49.6	47.3	50.8	45.1
Income from operations .....	5.4	11.3	3.7	13.0
Other income, net .....	2.0	1.9	2.5	2.0
Income before provision for income taxes ..	7.4	13.2	6.2	15.0
Provision for income taxes .....	(2.4)	(4.5)	(2.0)	(5.1)
Net income .....	5.0%	8.7%	4.2%	9.9%

Sales. Our sales increased 8% to \$6.5 million for the three months ended July 3, 1999 from \$6.0 million for the three months ended July 4, 1998. Sales increased 2% to \$12.2 million for the six months ended July 3, 1999 from \$11.9 million for the six months ended July 4, 1998. The growth in sales was primarily attributable to increased unit volume as the Company expanded its product offerings and expanded its customer base, offset in part by a decrease in external contract research sales not directly related to our core business. Domestic sales of \$3.7 million accounted for 57% of sales for the three months ended July 4, 1999 compared to \$3.8 million or 63% of sales in the comparable 1998 period. The decrease in domestic sales was due primarily to decreases in dermatology product sales and external contract research sales partially offset by an increase in ophthalmology product sales. International sales of \$2.8 million accounted for 43% of sales for the three months ended July 3, 1999 compared to \$2.2 million or 37% in the comparable 1998 period. The increase in international sales was primarily due to increases in dermatology product sales with increases in sales in all international regions. International ophthalmology product sales increased in most regions. Acceptance of the OcuLight GLx, which we started shipping in January 1999, contributed to the international sales increases. We expect revenues from international sales to continue to account for a substantial portion of our sales.

Gross Profit. Our gross profit increased 1% to \$3.6 million for the three months ended July 3, 1999 from \$3.5 million for the three months ended July 4, 1998. For the six months ended July 3, 1999, the company's gross profit decreased 4% to \$6.6 million as compared to \$6.9 million for the comparable period in 1998. Gross profit as a percentage of net sales for the three months ended July 3, 1999 decreased to 55%, compared to 59% for the three months ended July 4, 1998, due primarily to less external contract research sales which have higher average gross profit margins. In addition, we had increased international sales, which have lower gross profit margins and increased sales of resale products, such as our new ScanLite scanner for dermatology, which also have lower gross profit margins. We expect our gross profit margins to continue to fluctuate due to changes in the relative proportions of domestic and international sales, product mix, pricing, product costs and a variety of other factors.

Research and Development. Research and development expenses increased by 29% to \$0.9 million for the three months ended July 3, 1999 from \$0.7 million for the three months ended July 4, 1998, and increased as a percentage of net sales to 14% for the three months ended July 3, 1999 from 11% for the comparable prior year three-month period. For the six months ended July 3, 1999, research and development expenses increased 51% to \$1.8 million as compared to \$1.2 million for the six months ended July 4, 1998. The increase in research and development expenses during this period was primarily attributable to increases in personnel, clinical expenses and other resources as we increased our product development efforts. We expect these expenses for research and development to continue to increase in absolute dollars during the remainder of 1999 in connection with new product and clinical treatment development activities.

Sales, General and Administrative. Our sales, general and administrative expenses increased by 8% to \$2.3 million for the three months ended July 3, 1999 and remained the same as a percentage of net sales at 36% for the three months ended July 3, 1999 and for the comparable prior year three-month period. For the six months ended July 3, 1999, sales, general and administrative expenses increased by 5% to \$4.3 million as compared to \$4.1 million for the six months ended July 4, 1998. The increase in absolute dollars in sales, general and administrative expenses was primarily due to the hiring of additional sales employees to address new opportunities and to support expanding unit volumes for our medical products. We expect sales, general and administrative expenses to continue to increase in absolute dollars during the balance of 1999 to support the increasing unit shipment volumes and additional employees.

Income Taxes. Our effective tax rate for the three months ended July 3, 1999 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 available-for-sale security investments and tax benefits from our foreign sales corporation.

#### LIQUIDITY AND CAPITAL RESOURCES

At July 3, 1999, our primary sources of liquidity included cash and cash equivalents and available-for-sale securities of \$12.0 million. During the six months ended July 3, 1999, we generated \$1.1 million in cash and cash equivalents and available-for-sale securities. During this period, operating activities provided a net \$1.6 million of cash. Sources of cash from operating activities included a net increase in accounts payable and accrued expenses of \$0.7 million, a decrease in accounts receivable of \$0.8 million, net income of \$0.5 million, and depreciation and amortization of \$0.4 million, offset by uses of cash including an increase in inventories of \$0.8 million. The increase in inventory was primarily due to an increase in raw materials inventory. We generated \$1.5 million in investing activities during

the six months ended July 3, 1999, primarily from the net sales of \$1.8 million of available-for-sale securities offset by the acquisition of \$0.3 million of property and equipment and intangible assets. Net cash used in financing activities during the six months ended July 3, 1999 was \$133,000 which consisted of the purchase of \$232,000 of treasury stock offset by the issuance of common stock of \$99,000. We believe that, based on current estimates, our current cash and cash equivalents, and available-for-sale securities will be sufficient to meet our anticipated cash requirements for the next 12 months.

#### YEAR 2000 DISCLOSURE

We use a significant number of information technology ("IT") and non-IT systems in our internal operations. IT systems include applications for various financial, business and administrative functions and non-IT systems include those that have embedded technology in the systems. These systems may contain source code that is unable to properly interpret calendar years beginning with the upcoming year 2000. Systems that do not properly recognize such date-sensitive information may fail or create erroneous results. Also, we may be exposed to risks from systems of parties with whom we transact material business. Our products that we sell to our customers do not contain any internal embedded calendars in them and therefore we do not anticipate any problems related to the Year 2000 issue to develop with our products.

We are assessing our Year 2000 risk exposure and plan to implement remedial and corrective action where necessary. We have reviewed all of our major internal systems, including financial, business, administrative and manufacturing systems, to assess Year 2000 readiness and to identify critical systems that require correction or remediation. Based on the results of this assessment, we have installed a new ERP system and upgraded our phone system software to be fully Year 2000 compliant.

Also, we may be exposed to risks from systems of parties with whom we transact material business. We are working with critical suppliers of products and services to assess their Year 2000 readiness with respect both to their operations and the products and services they supply to us. Inquiries have been made and responses are being monitored, with appropriate follow up where required. This analysis will continue into 1999, with corrective action taken commensurate with the criticality of affected products and services. We depend significantly on revenue from sales of our products placed from customers from other countries. We do not know the extent to which Year 2000 problems will affect current and potential customers, whether international or domestic. A disruption in their business may cause a delay in or cancellation of orders that may adversely affect our business, financial condition or results of operations.

We are in the process of developing various contingency plans to address potential problems with critical internal systems and third party interactions. Our contingency plans include procedures for dealing with a major disruption of internal business systems, plans for long-term factory shutdown and identification of alternative vendors of critical materials in the event of Year 2000 related disruption in supply. Contingency planning will continue through 1999.

Our costs to date related to the Year 2000 issue consist of the costs of a new ERP system and phone system upgrade and the reallocation of internal resources to evaluate our Year 2000 situation, assess systems and make contingency plans. We have currently spent approximately \$400,000 on capital expenditures for the cost of software, hardware, external consulting fees and other related upgrades. We believe the costs of reallocation of internal resources to address this issue is immaterial based on the review of department budgets and staff allocations. We estimate that a maximum of \$40,000 will be needed to continue to assess, monitor, plan contingencies and make appropriate remediation, where needed. The estimate is based on our assessment of our systems and the responses of our critical third parties.

Based on currently available information, management does not believe that the Year 2000 issues discussed above related to internal systems or products sold to customers will have a material adverse impact on our financial condition or overall trends in results of operations. However, we are exposed to risks from third parties, both suppliers not delivering parts or services as expected and customers delaying or not ordering from us, and from interruptions of internal systems. Additionally, we may experience unknown system interruptions or have unplanned costs to correct unexpected problems. Any of these risks may result in a situation which may have material adverse effect on our business, financial condition or results of operations.

#### 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 dermatological market. We believe those 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.

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, Keeler Instruments, Inc. ("Keeler") and HGM Medical Laser Systems, Inc. ("HGM") and our principal competitors in dermatology are 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 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 1998 and 1997, our international sales were \$8.6 million and \$9.4 million, or 37% and 52%, respectively, of total sales. For the three months end July 3, 1999 and July 4, 1998, our international sales were \$2.8 million and \$2.2 million, representing 43% and 37%, 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 during 1998 on a quarterly basis 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
- o 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. 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 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 of this new photodynamic system will require approximately two years and 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 six 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 ("QSR"), 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 \$6.0 million per occurrence and an annual aggregate maximum of \$7.0 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.

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. We are assessing our Year 2000 risk exposure and plan to implement remedial and corrective action where necessary. We have reviewed all of our major internal systems, including financial, business, administrative and manufacturing systems, to assess Year 2000 readiness and to identify critical systems that require correction or remediation. Based on currently available information, management does not believe that the Year 2000 issues related to internal systems or products sold to customers will have a material adverse impact on our financial condition or overall trends in results of operations. However, we are exposed to risks from third parties, both suppliers not delivering parts or services as expected and customers delaying or not ordering from us and from interruptions of internal systems. Additionally, we may experience unknown system interruptions or have unplanned costs to correct unexpected problems. Any of these risks may result in a situation which may have a material adverse effect on our business, financial condition or results of operations. See "--Year 2000 Disclosure."

### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

Our exposure to market risk for changes in interest rates relate 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 3, 1999. 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 3, 1999, 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-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 17, 1999

By: /s/ Robert Kamenski

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

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6-MOS

	JAN-01-2000	
	JAN-03-1999	
	JUL-03-1999	8,737
		3,260
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