

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-QSB

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

For the quarterly period ended September 30, 1997

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 November 1, 1997 was 6,455,128.

## IRIDEX CORPORATION

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

	SEPTEMBER 30, 1997	DECEMBER 31, 1996
	-----	-----
ASSETS	(unaudited)	*
Current assets:		
Cash and cash equivalents	\$ 9,405	\$ 14,107
Available-for-sale securities	4,152	1,007
Accounts receivable, net	5,488	5,390
Inventories	3,261	1,859
Prepays and other current assets	483	122
Deferred income taxes	519	519
	-----	-----
Total current assets	23,308	23,004
Property and equipment, net	2,073	655
Deferred income taxes	48	48
	-----	-----
Total assets	\$ 25,429	\$ 23,707
	=====	=====
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,026	\$ 535
Accrued expenses	1,412	1,684
Current portion of capital lease obligations	5	8
	-----	-----
Total current liabilities	2,443	2,227
Capital lease obligations, net of current portion	--	2
	-----	-----
Total liabilities	2,443	2,229
	-----	-----
Stockholders' equity:		
Common Stock, \$.01 par value:		
Authorized: 30,000,000 shares;		
Issued and outstanding: 6,455,128 shares as of 9/30/97		
and 6,350,180 shares as of 12/31/96	64	63
Additional paid-in capital	21,484	21,248
Unrealized holding losses on available-for-sale securities	(24)	--
Retained earnings	1,462	167
	-----	-----
Total stockholders' equity	22,986	21,478
	-----	-----
Total liabilities and stockholders' equity	\$ 25,429	\$ 23,707
	=====	=====

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\*Derived from the 1996 audited financial statements.

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 SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	1997	1996	1997	1996
Sales	\$ 4,641	\$ 2,635	\$ 12,317	\$ 7,538
Cost of sales	1,987	968	5,267	2,848
Gross profit	2,654	1,667	7,050	4,690
Operating expenses:				
Research and development	422	313	1,314	914
Selling, general and administrative	1,458	1,177	4,182	3,342
Total operating expenses	1,880	1,490	5,496	4,256
Income from operations	774	177	1,554	434
Other income, net	157	226	472	524
Income before provision for income taxes	931	403	2,026	958
Provision for income taxes	(335)	(161)	(731)	(309)
Net income	\$ 596	\$ 242	\$ 1,295	\$ 649
Net income per share	\$ 0.09	\$ 0.04	\$ 0.19	\$ 0.10
Shares used in per share calculation	6,849	6,750	6,719	6,402

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

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

	NINE MONTHS ENDED SEPTEMBER 30,	
	----- 1997 -----	----- 1996 -----
Cash flows from operating activities:		
Net income	\$ 1,295	\$ 649
Adjustments to reconcile net income to net cash used in operating activities:		
Depreciation	261	142
Provision for doubtful accounts	10	(118)
Changes in operating assets and liabilities:		
Accounts receivable	(108)	(563)
Inventories	(1,402)	(1,040)
Prepays and other current assets	(361)	140
Accounts payable	491	72
Accrued expenses	(272)	(196)
	-----	-----
Net cash used in operating activities	(86)	(914)
	-----	-----
Cash flows from investing activities:		
Purchases of available-for-sale securities	(35,882)	(2,044)
Proceeds from sale of available-for-sale securities	32,713	1,000
Acquisition of property and equipment	(1,679)	(369)
	-----	-----
Net cash used in investing activities	(4,848)	(1,413)
	-----	-----
Cash flows from financing activities:		
Payment on capital lease obligations	(5)	(5)
Issuance of common stock, net	237	15,609
	-----	-----
Net cash provided by financing activities	232	15,604
	-----	-----
Net (decrease) increase in cash and cash equivalents	(4,702)	13,277
Cash and cash equivalents at beginning of period	14,107	1,227
	-----	-----
Cash and cash equivalents at end of period	\$ 9,405	\$ 14,504
	=====	=====
Supplemental schedule of non-cash investing activities:	(24)	--
Change in unrealized holding losses on available-for-sale on securities		

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

IRIDEX CORPORATION  
CONDENSED CONSOLIDATED  
NOTES TO FINANCIAL STATEMENTS

1. BASIS OF PRESENTATION

The condensed consolidated financial statements at September 30, 1997 and for the three months and nine month periods then ended are unaudited (except for the balance sheet information as of December 31, 1996, which is derived from the Company's audited financial statements) and reflect all adjustments (consisting only of normal recurring adjustments) which are, in the opinion of management, necessary for a fair presentation of the financial position and operating results for the interim periods. 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 the Company's Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission on March 25, 1997. The results of operations for the three and nine month periods ended September 30, 1997 are not necessarily indicative of the results for the year ending December 31, 1997, or any future interim period.

2. RECLASSIFICATIONS

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

3. INVENTORIES COMPRISE: (IN THOUSANDS)

	SEPTEMBER 30, 1997	DECEMBER 31, 1996
	-----	-----
	(UNAUDITED)	
Raw materials and work in progress	\$2,331	\$ 924
Finished goods	930	935
	-----	-----
Total inventories	\$3,261	\$1,859
	=====	=====

4. AVAILABLE - FOR- SALE SECURITIES

At September 30, 1997, available-for-sale securities consisted of five municipal securities due through March 1998.

5. RECENT ACCOUNTING PRONOUNCEMENTS

During February 1997, the Financial Accounting Standards Board issued Statement No. 128, "Earnings Per Share," (SFAS 128) which specifies the computation, presentation and disclosure requirements for earnings per share. SFAS 128 supersedes Accounting Principles Board Opinion No. 15 and will become effective for the Company's 1997 fiscal year. SFAS 128 requires restatement of all prior-period earnings per share data presented after the effective date. SFAS 128 is not expected to have a material impact on the Company's financial position, results of operations or cash flows.

In June 1997, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 130 (SFAS 130), Reporting Comprehensive Income. This statement establishes requirements for disclosure of comprehensive income and becomes effective for the Company's 1998 fiscal year, with reclassification of earlier financial statements for comparative purposes. Comprehensive income generally represents all changes in stockholders' equity except those resulting from investments or contributions by stockholders. The Company is evaluating alternative formats for presenting this information, but does not expect this pronouncement to materially impact the Company's results of operations.

In June 1997, The Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 131 (SFAS 131), Disclosures about Segments of an Enterprise and Related Information. This statement establishes standards for disclosure about operating segments in annual financial statements and selected information in interim financial reports. It also establishes standards for related disclosures about products and services, geographic areas and major customers. This statement supersedes Statement of Financial Accounting Standards No. 14, Financial Reporting for Segments of a Business Enterprise. The new standard becomes effective for the Company's 1998 fiscal year and requires that comparative information from earlier years be restated to conform to the requirements of this standard. The Company is evaluating the requirements of SFAS 131 and the effects, if any, on the Company's current reporting and disclosures.

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 Affecting 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 the Company's income statement for the periods indicated.

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	1997	1996	1997	1996
	-----	-----	-----	-----
Sales .....	100.0%	100.0%	100.0%	100.0%
Cost of sales .....	42.8	36.7	42.8	37.8
	-----	-----	-----	-----
Gross profit .....	57.2	63.3	57.2	62.2
Operating expenses:				
Research and development .....	9.1	11.9	10.7	12.1
Sales, general and administrative ...	31.4	44.7	33.9	44.4
	-----	-----	-----	-----
Total operating expenses .....	40.5	56.6	44.6	56.5
	-----	-----	-----	-----
Income from operations .....	16.7	6.7	12.6	5.7
Other income, net .....	3.4	8.6	3.8	7.0
	-----	-----	-----	-----
Income before provision for income taxes	20.1	15.3	16.4	12.7
Provision for income taxes .....	(7.3)	(6.1)	(5.9)	(4.1)
	-----	-----	-----	-----
Net income .....	12.8%	9.2%	10.5%	8.6%
	=====	=====	=====	=====

Sales. Sales increased 76% to \$4.6 million for the three months ended September 30, 1997 from \$2.6 million for the three months ended September 30, 1996. Sales increased 63% to \$12.3 million for the nine months ended September 30, 1997 from \$7.5 million for the nine months ended September 30, 1996. The growth in sales over these periods was primarily attributable to increased unit volume as the Company expanded its product offerings and broadened its customer base, offset somewhat by slight decreases in average selling prices. International sales of \$2.8 million accounted for 60% of sales in the three months ended September 30, 1997 compared to \$1.3 million or 48% of sales in the comparable 1996 period. The Company expects revenues from international sales to continue to account for a substantial portion of its sales. While the OcuLight GL was introduced in the third quarter of 1996, the Company's ability to ship the OcuLight GL in volume during the first half of 1997 was negatively affected by delivery problems with a sole source component. The Company qualified a second source for that component and began to receive shipments from the second source supplier in the second quarter of 1997. The Company believes that deliveries from the two diode sources should meet its requirements for the balance of 1997. The Company expects future growth in sales to be primarily derived



from sales of the OcuLight GL and the DioLite 532 Dermatology Laser (the "DioLite 532") which the Company shipped in greater volumes during the third quarter of 1997.

**Gross Profit.** The Company's gross profit increased 59% to \$2.7 million for the three months ended September 30, 1997 from \$1.7 million for the three months ended September 30, 1996. For the nine months ended September 30, 1997 gross profit increased 50% to \$7.1 million from \$4.7 million for the three months ended September 30, 1996. Gross profit as a percentage of net sales for the three months ended September 30, 1997 decreased to 57%, as compared to 63% for the three months ended September 30, 1996, due primarily to increased costs incurred to support expansion of the Company's business and the introduction of the OcuLight GL. In addition, increasing competition and a larger than expected percentage of international sales has resulted in a slight downward trend in average selling prices of the Company's products. Gross profit as a percentage of net sales for the nine months ended September 30, 1997 was 57% as compared to 62% for the nine months ended September 30, 1996. While the Company expects continued competitive pressure on the prices of its products, it expects the percentage of international sales to stabilize during the remainder of 1997. The Company intends to continue its efforts to reduce the cost of components and the costs associated with new product introductions and thereby mitigate the impact of price reductions on its gross profits. The Company expects its gross profit to continue to fluctuate due to changes in the relative proportions of domestic and international sales, costs associated with additional new product introductions, pricing and a variety of other factors.

**Research and Development.** Research and development expenses increased by 35% to \$0.4 million for the three months ended September 30, 1997 from \$0.3 million for the three months ended September 30, 1996, but decreased as a percentage of net sales to 9% for the three months ended September 30, 1997 from 12% for the comparable prior year three month period. For the nine months ended September 30, 1997, research and development expenses increased 44% to \$1.3 million from \$0.9 million for the nine months ended September 30, 1996, but decreased as a percentage of net sales to 11% for the nine months ended September 30, 1997 from 12% for the comparable prior year nine month period. The increase in research and development expenses during this period was primarily attributable to an increase in personnel as the Company strengthened its product development efforts, particularly those directed at the introduction of the OcuLight GL and the DioLite 532. The Company expects these expenses for research and development to continue to increase in absolute dollars during the remainder of 1997 in connection with new product development activities.

**Sales, General and Administrative.** Sales, general and administrative expenses grew by 24% to \$1.5 million for the three months ended September 30, 1997 from \$1.2 million for the three months ended September 30, 1996, decreased as a percentage of net sales to 31% for the three months ended September 30, 1997 from 45% for the comparable prior year three month period. For the nine months ended September 30, 1997, selling, general and administrative expenses increased 25% to \$4.2 million from \$3.3 million for the nine months ended September 30, 1996, but decreased as a percentage of net sales to 34% for the nine months ended September 30, 1997 from 44% for the comparable prior year nine month period. The increases in sales, general and administrative expenses were primarily due to the hiring of additional marketing and administrative employees to address new opportunities, to support expanding unit volumes and the expenses associated with the OcuLight GL and the DioLite 532. During 1995, the Company began implementing a new management information system in manufacturing and expects to continue to expand the implementation of this or another system throughout the Company through the first half of 1998. The Company expects sales, general and administrative expenses to continue to increase during the balance of 1997 to support the increasing unit shipment volumes and additional employees.

**Income Taxes.** The Company's effective tax rates for the three and nine months ended September 30, 1997 were 36%. This rate differs from the federal statutory rate primarily due to state income taxes, partially

offset by the utilization of tax credits, non-taxable available-for-security investments and tax benefits from the Company's foreign sales corporation.

#### RECENT ACCOUNTING PRONOUNCEMENTS

During February 1997, the Financial Accounting Standards Board issued Statement No. 128, "Earnings Per Share," (SFAS 128) which specifies the computation, presentation and disclosure requirements for earnings per share. SFAS 128 supersedes Accounting Principles Board Opinion No. 15 and will become effective for the Company's 1997 fiscal year. SFAS 128 requires restatement of all prior-period earnings per share data presented after the effective date. SFAS 128 is not expected to have a material impact on the Company's financial position, results of operations or cash flows.

In June 1997, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 130 (SFAS 130), Reporting Comprehensive Income. This statement establishes requirements for disclosure of comprehensive income and becomes effective for the Company for fiscal years beginning after December 15, 1997, with reclassification of earlier financial statements for comparative purposes. Comprehensive income generally represents all changes in stockholders' equity except those resulting from investments or contributions by stockholders. The Company is evaluating alternative formats for presenting this information, but does not expect this pronouncement to materially impact the Company's results of operations.

In June 1997, The Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 131 (SFAS 131), Disclosures about Segments of an Enterprise and Related Information. This statement establishes standards for disclosure about operating segments in annual financial statements and selected information in interim financial reports. It also establishes standards for related disclosures about products and services, geographic areas and major customers. This statement supersedes Statement of Financial Accounting Standards No. 14, Financial Reporting for Segments of a Business Enterprise. The new standard becomes effective for fiscal years beginning after December 15, 1997, and requires that comparative information from earlier years be restated to conform to the requirements of this standard. The Company is evaluating the requirements of SFAS 131 and the effects, if any, on the Company's current reporting and disclosures.

#### LIQUIDITY AND CAPITAL RESOURCES

At September 30, 1997, the Company's primary sources of liquidity included cash and cash equivalents and available-for-sale securities of \$13.6 million.

During the nine months ended September 30, 1997, the Company used \$0.1 million in operating activities. Sources of cash included net income of \$1.3 million, depreciation of \$0.3 million and increases in accounts payable of \$0.5 million, offset by increases in inventories of \$1.4 million, increases in prepaid expenses of \$0.5 million and decreases in accrued expenses of \$0.3 million. The increase in inventories is primarily due to the purchase of components for the Company's new dermatology product, the DioLite, which the Company shipped in greater volume during the third quarter of 1997. Additional supplies of components have also been purchased for the OcuLight GL, shipments of which were delayed in the first quarter due to the unavailability of a sole source component. The Company has qualified a second source for that component and received deliveries from that second source during the second and third quarters. The Company expects that deliveries from the two sources should meet the Company's requirements for such diode components.

The Company used \$4.9 million in investing activities during the nine months ended September 30, 1997. Investing activities consisted of the acquisition of \$1.7 million of property and equipment and leasehold improvements of which \$1.3 million were used in relocating the Company to a larger facility, and net acquisition of \$3.2 million of available-for-sale securities.

In February 1996, the Company sold 1,982,500 shares of its Common Stock in connection with its initial public offering ("IPO"). The net proceeds of this offering were approximately \$15.7 million after deducting underwriting discounts and commissions and expenses of the offering. The Company has used a portion of the net proceeds from the IPO for purchases of inventory, leasehold improvements and payment of certain accrued liabilities. The Company believes that, based on current estimates, its current cash and cash equivalents, and available-for-sale securities will be sufficient to meet its anticipated cash requirements through 1998.

#### FACTORS THAT MAY AFFECT FUTURE RESULTS

**Dependence on Visible Photocoagulator.** The Company introduced a new semiconductor-based photocoagulator system, the OcuLight GL, in the second half of 1996. The Company devoted significant resources to the development and commercial introduction of the OcuLight GL. The Company believes that the continued growth of its sales, if any, will be substantially dependent upon sales of this visible light laser system and other new products. While the OcuLight GL has been successfully introduced, the Company has continued to face risks associated with developing and manufacturing a new product. For example, the Company experienced delays in its manufacturing of the OcuLight GL due to the inability of a supplier of a sole-source component to deliver components in volume and on a timely basis. The Company has worked with this supplier to resolve these difficulties and has qualified a second source for that component. The Company began to ship products incorporating components from this second source during the second quarter of 1997 and believes that it can obtain adequate supplies of this component on a timely basis. Other difficulties may occur, for example, despite testing by the Company, quality and reliability problems may arise which may result in reduced bookings, manufacturing rework costs, delays in collecting accounts receivable, additional service and warranty costs and a decline in the Company's competitive position. Moreover, the Company believes that recommendations by ophthalmologists and clinicians for use of this laser will be essential for its continued market acceptance. While the Company believes that the OcuLight GL has been generally accepted by the market, ophthalmologists and clinicians may not recommend this laser or related treatments unless they conclude, based upon clinical data and other factors, that it is a beneficial alternative to other technologies and treatments, including more established argon gas lasers. There can be no assurance that the Company will be able to manufacture this visible laser system on a cost-effective, timely basis or that it will achieve widespread market acceptance. Additionally, the OcuLight GL competes directly with established ion-based and other photocoagulator systems currently sold by the Company's competitors and new systems being introduced by competitors and the Company expects to continue to experience significant competitive pressures. Failure of the OcuLight GL system to achieve widespread market acceptance for any reason would have a material adverse effect on the Company's business, results of operations and financial condition.

**Dependence on Continued Market Acceptance of Infrared Photocoagulators.** Prior to the third quarter of 1996, substantially all of the Company's revenues had been derived from sales of its OcuLight Diode Laser Photocoagulator system (the "OcuLight SL"), an infrared, invisible light, semiconductor-based laser console and interchangeable delivery devices, into the ophthalmic medical device market. The ophthalmic community historically has used argon-gas photocoagulators which produce visible light and the substantial majority of photocoagulators sold for ophthalmic purposes are argon-gas. Because sales of the Company's OcuLight SL continued to represent a significant portion of the infrared laser market, increased sales of the Company's infrared

system will depend on the rate at which users convert to infrared photocoagulators. Equipment purchasing decisions may be based on a number of factors, in addition to price and performance. For example, many ophthalmologists have been trained in medical school to use visible lasers and may be reticent to change to infrared lasers. There can be no assurance that the OcuLight SL will continue to be accepted by the market or that other competitive treatments will not be developed, and therefore that sales derived from the OcuLight SL will continue to grow at historical rates or be sustainable at current sales levels. Any decline in the demand for the OcuLight SL or any failure of sales derived from such products to meet the Company's expectations would have a material adverse effect on the business, results of operations and financial condition of the Company.

**Introduction and Market Acceptance of DioLite 532.** In 1996, the Company developed a new laser product which is intended to be used in the dermatology market to treat vascular and pigmented skin lesions. The new product, the DioLite 532, delivers pulsed laser power through a variety of fiber optic delivery device hand pieces. While the Company has increased production of the DioLite 532 during the third quarter of 1997, there can be no assurance that such products will achieve a sufficient level of clinical or market acceptance or that the Company can properly manage the successful introduction of such product into the dermatology market, a market that the Company's products do not currently address and in which the Company has limited experience. Additionally, there can be no assurance that the Company will be able to manufacture this laser product on a cost-effective, timely basis or that it will achieve widespread market acceptance.

**Management of Growth.** With the introduction of the OcuLight GL and the DioLite 532, the Company has recently experienced, and may continue to experience growth in production, the number of employees, the scope of its business, its operating and financial systems and the geographic area of its operations. This growth has resulted in new and increased responsibilities for management personnel and has placed and continues to place a significant strain upon the Company's management, operating, inventory and financial systems and resources. To accommodate recent growth and to compete effectively and manage future growth, if any, the Company has been required to continue to implement and improve operational, financial and management information systems, procedures and controls and to expand, train, motivate and manage its work force. The Company has been implementing a new management information system in manufacturing and expects to continue to expand the implementation of this or another system throughout the Company through the first half of 1998. The Company's future success will depend on the successful installation of these systems as well as on the ability of its current and future executive officers to operate effectively, both independently and as a group. There can be no assurance that the Company's personnel, systems, procedures and controls will be adequate to support the Company's existing and future operations. Any failure to implement and improve the Company's operational, financial and management systems or to expand, train, motivate or manage employees could have a material adverse effect on the Company's business, results of operations and financial condition.

**Dependence on Development of New Products and New Applications.** The Company's future success is dependent upon, among other factors, its ability to develop, obtain regulatory approval, manufacture and introduce on a timely and cost-effective basis as well as 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, including price, safety, efficacy, reliability, marketing and sales efforts, the development of new applications for these products and general economic conditions affecting purchasing patterns. Even if the Company's products achieve clinical acceptance, there can be no assurance that the Company can successfully manage the introduction of such products into the ophthalmic or other markets. In 1996, the Company developed a new product which is intended to be used in the dermatology market to treat vascular and pigmented skin lesions. The new product, the DioLite 532, delivers pulsed laser power through a variety of fiber optic delivery device hand pieces. While the Company has increased production of the DioLite 532 during the third quarter of 1997, there can be no assurance

that such products will achieve clinical or market acceptance or that the Company can properly manage the successful introduction of such product into the dermatology market, a market that the Company's products do not currently address and in which the Company has limited experience. The failure of the Company to successfully develop and introduce new products or enhanced versions of existing products could have a material adverse effect on the Company's business, operating results and financial condition. The Company is seeking to expand the market for its existing and new products by working with clinicians and third parties to identify new applications for its products, validating new procedures which utilize its products and responding more effectively to new procedures. There can be no assurance that the Company's efforts to develop new applications for its products will be successful, that it can obtain regulatory approvals to use its products in new clinical applications in a timely manner, or at all, or gain satisfactory market acceptance for such new applications. Failure to develop and achieve market acceptance of new applications or new products would have a material adverse effect on the Company's business, results of operations and financial condition.

**Dependence on Key Manufacturers and Suppliers.** The Company relies on third parties to manufacture substantially all of the components used in its products, although the Company assembles critical subassemblies as well as the final product at its 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 components such as optics and laser diodes and potentially reduced control of quality, production costs and the timing of delivery. The Company has qualified two or more sources for most of the components used in its products. Certain diodes purchased from SDL, Inc. ("SDL") were not readily available from other suppliers until the second quarter of 1997. During the last half 1996 and first quarter 1997, the Company experienced delays in its manufacturing of the OcuLight GL due to the inability of SDL to deliver components in volume and on a timely basis. The Company continues to work with this supplier to ensure such difficulties do not reoccur. Additionally, during the first quarter of 1997, the Company qualified Opto-Power as a second source in this diode component. This component is also required for the DioLite 532, which the Company shipped in greater volumes in the third quarter of 1997. Deliveries from SDL and Opto-Power should meet the Company's future requirements for such diode components. The process of qualifying suppliers is ongoing and may be lengthy, particularly as new products are introduced. The Company does not have long-term or volume purchase agreements with any of its suppliers and currently purchases components on a purchase order basis. No assurance can be given that these components will be available in the quantities required by the Company, on reasonable terms, or at all. Establishing its own capabilities to manufacture these components would require significant scale-up expenses and additions to facilities and personnel and could significantly decrease the Company's profit margins. The Company's business, results of operations and financial condition would be adversely affected if it is unable to continue to obtain components as required at a reasonable cost.

**Quarterly Fluctuations in Operating Results.** Although the Company has been profitable on an annual and quarterly basis for the last four years, the Company's sales and operating results have varied substantially on a quarterly basis and such fluctuations are expected to continue in future periods. The Company believes that its gross margins in 1997 will continue to be lower than gross margins in 1996, primarily because of increases in international sales, increases in costs incurred to support expansion of the Company's business, capital expenditures associated with the Company's move to its new facility, the higher cost of certain components associated with the OcuLight GL, the introduction of the DioLite 532 and the slight downward trend in average selling prices, primarily due to increased competition. The Company expects international sales of the OcuLight GL to continue to exceed domestic sales of this product during the balance of 1997. The gross margins on international shipments of the OcuLight GL are significantly lower than the gross margins on domestic shipments of the OcuLight GL, primarily due to distributor discounts. Additionally, the Company expects to continue to incur increased operating expenses in the balance of 1997 associated with the introduction of the OcuLight GL and DioLite 532. Such increases may result in lower operating margins in the fourth quarter of 1997. The ability

of the Company to increase its operating margins during the fourth quarter of 1997 and thereafter will depend primarily on timely receipt of components from its two diode sources and other critical components, successful and timely manufacturing of the OcuLight SL, OcuLight GL and DioLite 532 and continued market acceptance of the OcuLight GL and DioLite 532, as well as increased sales of the OcuLight SL. The Company's operating results are affected by a number of factors, many of which are beyond the Company's control. Factors contributing to these fluctuations include the timing of the introduction and market acceptance of new products or product enhancements by the Company and its competitors, the cost and availability of components and subassemblies, changes in pricing by the Company and its competitors, the timing of the development and market acceptance of new applications for the Company's products, the relatively long and highly variable sales cycle for the Company's products to hospitals and other health care institutions, fluctuations in economic and financial market conditions and resulting changes in customers' or potential customers' budgets and increased product development costs. Any inability to obtain adequate quantities of the critical components used in the system products would adversely impact the Company's ability to ship the OcuLight SL, OcuLight GL and the DioLite 532. In addition to these factors, the Company's quarterly results have been and are expected to continue to be affected by seasonal factors. For example, domestic sales of ten decline slightly prior to the meeting of the American Academy of Ophthalmology in October. The Company manufactures its products to forecast rather than to outstanding purchase orders, and products are typically shipped shortly after receipt of a purchase order. While backlog increased in 1996 and during the first half of 1997, because of manufacturing difficulties associated with the Company's new product, the Company does not expect significant backlog in the future and the amount of backlog at any particular date is generally not indicative of its future level of sales. Although the Company's manufacturing procedures are designed to assure rapid response to customer orders, they may in certain instances create a risk of excess or inadequate inventory levels if orders do not match forecasts. The Company increased its inventory of the OcuLight SL system during 1996 in anticipation of allocating substantial manufacturing resources to producing the OcuLight GL. As of September 30, 1997, the Company no longer maintains an excess inventory level of manufactured OcuLight SL systems. The Company's expense levels are based, in part, on expected future sales. If sales levels in a particular quarter do not meet expectations, the Company may be unable to adjust operating expenses quickly enough to compensate for the shortfall, and the Company's results of operations may be adversely affected. In addition, the Company has historically made a significant portion of each quarter's product shipments near the end of the quarter. If that pattern continues, even short delays in shipment of products at the end of a quarter 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 the Company will remain profitable in the future or that operating results will not vary significantly.

Competition. Competition in the market for devices used for ophthalmic treatments is intense and is expected to increase. This market is also characterized by rapid technological innovation and change and the Company's products could be rendered obsolete as a result of future innovations. The Company's competitive position depends on a number of factors including product performance, characteristics and functionality, ease of use, scalability, durability and cost. In addition to photocoagulators, the Company competes with pharmaceuticals, other technologies and other surgical techniques. Although many of the Company's current competitors do not currently sell semiconductor lasers such as those used in the Company's products, the Company believes that competitors will be introducing competitive products and may compete directly with the Company. The Company's principal competitors are Coherent, Inc., Nidek, Zeiss, Alcon International, Keeler and HGM Medical Laser Systems, Inc. Of these companies, only Nidek, Zeiss, Alcon International and Keeler currently offer a semiconductor-based laser system. Other competitors have substantially greater financial, engineering, product development, manufacturing, marketing and technical resources than the Company. Such companies also have greater name recognition than the Company and long-standing customer relationships. In addition, there can be no assurance

that other medical companies, academic and research institutions or others will not develop new technologies or therapies, including medical devices, surgical procedures or pharmacological treatments and obtain regulatory approval for products utilizing such techniques that are more effective in treating the ophthalmic conditions targeted by the Company or are less expensive than the Company's current or future products, and that the Company's technologies and products would not be rendered obsolete by such developments. Any such developments could have a material adverse effect on the business, financial condition and results of operations of the Company.

**Dependence on Collaborative Relationships.** The Company has entered into collaborative relationships with academic medical centers and physicians in connection with the research and development and clinical testing of its products. The Company plans to collaborate with third parties to develop and commercialize existing and new products. In May 1996, the Company executed an agreement with Miravant Medical Technologies, formerly known as PDT Corporation, ("MRVT"), a maker of photodynamic drugs, under which the Company and MRVT have collaborated to develop a device which will emit a laser beam to activate a photodynamic drug being developed by MRVT to achieve a desired therapeutic result. The development of this new photodynamic system will require at least three years and significant financial and other resources. There can be no assurance that this collaborative development effort will continue or that it will result in the successful development and introduction of a photodynamic system. The Company believes that these current and future relationships are important because they would allow the Company greater access to funds, to research, development and testing resources and to manufacturing, sales and distribution resources. However, the amount and timing of resources to be devoted to these activities are not within the Company's control. There can be no assurance that such parties will perform their obligations as expected or that the Company's reliance on others for clinical development, manufacturing and distribution of its products will not result in unforeseen problems. Further, there can be no assurance that the Company's collaborative partners will not develop or pursue alternative technologies either on their own or in collaboration with others, including the Company's competitors, as a means of developing or marketing products for the diseases targeted by the collaborative programs and by the Company's products. The failure of any current or future collaboration efforts could have a material adverse effect on the Company's ability to introduce new products or applications and therefore could have a material adverse effect on the Company's business, results of operations and financial condition.

**Dependence on International Sales.** The Company derives, and expects to continue to derive, a large portion of its revenue from international sales. In 1995, 1996 and nine months ended September 30, 1997, the Company's international sales were \$4.3 million, \$6.1 million, and \$6.9 million, or 49%, 50% and 56%, respectively, of total sales. Therefore, a large portion of the Company's revenues will continue to be subject to the risks associated with international sales, including fluctuations in foreign currency exchange rates, shipping delays, generally longer receivables collection periods, changes in applicable regulatory policies, international monetary conditions, domestic and foreign tax policies, trade restrictions, duties and tariffs, and economic and political instability. Each of these factors could have a significant impact on the Company's ability to deliver products on a competitive and timely basis.

**Patents and Proprietary Rights.** The Company's success and ability to compete is dependent in part upon its proprietary information. The Company relies on a combination of patents, trade secrets, copyright and trademark laws, nondisclosure and other contractual agreements and technical measures to protect its intellectual property rights. The Company files patent applications to protect technology, inventions and improvements that are significant to the development of its business. The Company has been issued six United States patents on the technologies related to its products and processes. The Company has applied for two additional patents related to its solid state laser products. There can be no assurance that any of the Company's patent applications will issue as patents, that any patents now or hereafter held by the Company will offer any degree of protection,

or that the Company's patents or patent applications will not be challenged, invalidated or circumvented in the future. Moreover, there can be no assurance that the Company's competitors, many of which have substantial resources and have made substantial investments in competing technologies, will not seek to apply for and obtain patents that will prevent, limit or interfere with the Company's ability to make, use or sell its products either in the United States or in international markets.

In addition to patents, the Company relies on trade secrets and proprietary know-how which it seeks to protect, in part, through proprietary information agreements with employees, consultants and other parties. The Company's proprietary information agreements with its employees and consultants contain industry standard provisions requiring such individuals to assign to the Company without additional consideration any inventions conceived or reduced to practice by them while employed or retained by the Company, subject to customary exceptions. There can be no assurance that proprietary information agreements with employees, consultant and others will not be breached, that the Company would have adequate remedies for any breach, or that the Company's trade secrets will not otherwise 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 and 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 competitors of the Company. 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, the Company has not conducted any searches to determine whether the Company's technology infringes any patents or patent applications. The Company has from time to time been notified of, or has otherwise been made aware of claims that it may be infringing upon patents or other proprietary intellectual property owned by others. If it appears necessary or desirable, the Company may seek licenses under such patents or proprietary intellectual property. Although patent holders commonly offer such licenses, no assurance can be given that licenses under such patents or intellectual property will be offered or that the terms of any offered licenses will be reasonable or will not adversely impact the Company's 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 the Company 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 the Company from manufacturing and selling its products, which would have a material adverse effect on the Company's business, results of operations and financial condition. Conversely, litigation may be necessary to enforce patents issued to the Company, to protect trade secrets or know-how owned by the Company 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.

**Government Regulation.** The medical devices marketed and manufactured by the Company are subject to extensive regulation by the FDA and, in some instances, by foreign and state governments. Pursuant to the Federal Food, Drug and Cosmetic Act of 1976, as amended, and the regulations promulgated thereunder, the FDA regulates the 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 the Company's expectations due to the longer than expected time period required to obtain FDA premarket clearance.



Noncompliance with applicable requirements, including good manufacturing practices ("GMP"), 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 manufactured or distributed by the Company. The failure of the Company to obtain government approvals or any delays in receipt of such approvals would have a material adverse effect on the Company's business, results of operations and financial condition.

Product Liability and Insurance. The Company may be subject to product liability claims in the future. The Company's products are highly complex, used to treat extremely delicate eye tissue and are often used in situations where there is a high risk of serious injury or adverse side effects. In addition, although the Company recommends that its disposable products only be used once and so prominently labels these disposables, the Company believes that certain customers may reuse these disposables. Were such a disposable not adequately sterilized by the customer between such uses, a patient could suffer serious consequences, possibly resulting in a suit against the Company for damages. Accordingly, the manufacture and sale of medical products entails significant risk of product liability claims. Although the Company maintains product liability insurance with coverage limits of \$5.0 million per occurrence and an annual aggregate maximum of \$6.0 million, there can be no assurance that the coverage of the Company's insurance policies will 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 the Company in excess of its insurance coverage could have a material adverse effect on the Company's business, results of operations and financial condition. To date, the Company has not experienced any product liability claims.

Volatility of Stock Price. The trading price of the Company's Common Stock has been subject to wide fluctuations in response to a variety of factors since the Company's initial public offering in February 1996, including quarterly variations in operating results, announcements of technological innovations or new products by the Company or its competitors, developments in patents or other intellectual property rights, general conditions in the ophthalmic laser industry, revised earning estimates, comments or recommendations issued by analysts who follow the Company, its competitors or the ophthalmic laser industry and general economic and market conditions. Additionally, the stock market in general, and the market for technology stocks in particular, have experienced extreme price volatility in recent years. 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 the Common Stock.

PART II. OTHER INFORMATION

ITEM 4. SUBMISSION OF MATTERS TO VOTE OF SECURITY HOLDERS

None.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

11.1 Statement Regarding Computation of Net Income Per Share

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: November 13, 1997

By: /s/ Robert Kamenski

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

## INDEX TO EXHIBITS

EXHIBIT		PAGE
11.1	Statement Regarding Computation of Net Income Per Share	21
27.1	Financial Data Schedule	22

IRIDEX CORPORATION AND SUBSIDIARIES  
 COMPUTATION OF NET INCOME PER SHARE  
 (IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30	
	1997	1996	1997	1996
Weighted average shares outstanding				
Common stock .....	6,427	6,339	6,390	4,860
Conversion of preferred stock .....	--	--	--	946
Common equivalent shares pursuant to Staff Accounting .....				
Bulletin No. 83(2) .....	--	--	--	273
Conversion of stock options under the treasury stock method .....	422	411	329	323
Weighted average common shares and equivalents .....	6,849	6,750	6,719	6,402
Net income .....	\$ 596	\$ 242	\$1,295	\$ 649
Net income per share(1) .....	\$ .09	\$ .04	\$ .19	\$ .10

- (1) There is no difference between primary and fully diluted net income per share.
- (2) Pursuant to Securities & Exchange Commission's Staff Accounting Bulletin No. 83, all securities issued during the period from January 17, 1995 through the filing date of the initial public offering (January 16, 1996), are included in the calculation of Common Stock equivalents as if outstanding for all periods prior to the effective date of the initial public offering (February 15, 1996), even if anti-dilutive. The Common Stock warrants of stock options are computed using the Treasury Stock Method, using the estimated initial public offering price and applicable exercise prices.

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JAN-01-1997

SEP-30-1997

9,405

4,152

5,838

(350)

3,261

23,308

2,905

(832)

25,429

2,443

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1,438

25,429

12,317

12,317

5,267

5,267

5,496

0

0

2,026

(731)

1,295

0

0

0

1,295

.19

.19