Washington, D.C. 20549

FORM 10-Q
[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 1998
[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
For the Transition period from to

Commission File Number: 0-27598
IRIDEX CORPORATION
(Exact name of registrant as specified in its charter)

## Delaware

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(State or other jurisdiction of incorporation or organization)

## 77-0210467

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

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1212 TERRA BELLA AVENUE
MOUNTAIN VIEW, CALIFORNIA 94043-1824
(Address of principal executive offices, including zip code)
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(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.
Yes [X] No [ ]

The number of shares of Common Stock, $\$ .01$ par value, issued and outstanding as of May 11, 1998 was 6,467,287.

## IRIDEX CORPORATION

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## IRIDEX CORPORATION

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

|  | $\begin{gathered} \text { MARCH 31, } \\ 1998 \end{gathered}$ | $\begin{gathered} \text { DECEMBER 31, } \\ 1997 \end{gathered}$ |
| :---: | :---: | :---: |
| ASSETS | (unau |  |

Current assets:
Cash and cash equivalents
Available-for-sale securities

| \$ 10,199 | \$ 9,900 |
| :---: | :---: |
| 2,548 | 3,588 |
| 7,072 | 6,057 |
| 4,514 | 3,976 |
| 492 | 451 |
| 550 | 550 |
| 25,375 | 24,522 |
| 2,331 | 2,133 |
| 31 | 31 |
| \$ 27,737 | \$ 26,686 |

LIABILITIES AND STOCKHOLDERS' EQUITY
Current liabilities:
Accounts payable $\quad 994$
Accrued expenses $\quad 2,121 \quad 2,051$
Capital lease obligations
Total liabilities
3,117
2,806

Stockholders' equity:
Common Stock, \$.01 par value:
Authorized: 30,000,000 shares;
Issued and outstanding: 6,465,558 shares as of 3/31/98 and $6,455,483$ shares as of $12 / 31 / 97$

65
65
Additional paid-in capital
Unrealized losses on available-for-sale securities 21,637
(2)

Retained earnings
2,920
21,552
(2)

2,265
Total stockholders' equity
Total liabilities and stockholders' equity
-------- -------
24,620 23,880
-------- -------
\$ 27,737 \$ 26,686
========
========
*Derived from the 1997 audited financial statements.

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

|  | THREE MONTHS ENDED MARCH 31, |  |
| :---: | :---: | :---: |
|  | 1998 | 1997 |
| Sales | \$ 5,872 | \$ 3,320 |
| Cost of sales | 2,490 | 1,437 |
| Gross profit | 3,382 | 1,883 |
| Operating expenses: |  |  |
| Research and development | 546 | 421 |
| Selling, general and administrative | 1,975 | 1,324 |
| Total operating expenses | 2,521 | 1,745 |
| Income from operations | 861 | 138 |
| Other income, net | 131 | 155 |
| Income before provision for income taxes | 992 | 293 |
| Provision for income taxes | (337) | (108) |
| Net income | \$ 655 | \$ 185 |
| Net income per common share | \$ 0.10 | \$ 0.03 |
| Net income per common share-assuming dilution | \$ 0.10 | \$ 0.03 |
| Shares used in per common share calculation | 6,459 | 6,356 |
| Shares used in per common share-assuming dilution calculation | 6,812 | 6,640 |

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

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

|  | THREE MONTHS ENDED MARCH 31, |  |  |  |
| :---: | :---: | :---: | :---: | :---: |
|  |  | 1998 |  | 1997 |
| Cash flows from operating activities: |  |  |  |  |
| Net income | \$ | 655 | \$ | 185 |
| Adjustments to reconcile net income to net cash used in activities: |  |  |  |  |
| Depreciation |  | 166 |  | 80 |
| Provision for doubtful accounts |  | (20) |  | 25 |
| Changes in operating assets and liabilities: |  |  |  |  |
| Accounts receivable |  | (995) |  | 412 |
| Inventories |  | (538) |  | (191) |
| Prepaids and other current assets |  | (41) |  | (171) |
| Accounts payable |  | 242 |  | (94) |
| Accrued expenses |  | 70 |  | (792) |
| Net cash used in operating activities |  | (461) |  | ----- |
| Cash flows from investing activities: |  |  |  |  |
| Purchases of available-for-sale securities |  | $(9,689)$ |  | $(4,810)$ |
| Proceeds from sale of available-for-sale securities |  | 10,729 |  | 4,740 |
| Acquisition of property and equipment |  | (364) |  | (64) |
| Net cash provided by (used in) investing activities |  | 676 |  | (134) |
| Cash flows from financing activities: |  |  |  |  |
| Payment on capital lease obligations |  | (1) |  | (2) |
| Issuance of common stock, net |  | 85 |  | 1 |
| Net cash provided by (used in) financing activities |  | 84 |  | (1) |
| Net increase (decrease) in cash and cash equivalents |  | 299 |  | (681) |
| Cash and cash equivalents at beginning of period |  | 9,900 |  | 4,963 |
| Cash and cash equivalents at end of period | \$ | 10,199 | \$ | 4,282 |

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

## 1. BASIS OF PRESENTATION

The condensed consolidated financial statements at March 31, 1998 and for the three month period then ended are unaudited (except for the balance sheet information as of December 31, 1997, 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 31, 1998. The results of operations for the three month period ended March 31, 1998 are not necessarily indicative of the results for the year ending December 31, 1998, 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)

| MARCH 31, DECEMBER 31, |  |
| :---: | :---: |
| 1998 | 1997 |
| ---------- |  |

Raw materials and work in progress

| $\$ 2,541$ | $\$ 2,579$ |
| ---: | ---: |
| 1,973 | 1,397 |
| ----- | ----- |
| $\$ 4,514$ | $\$ 3,976$ |
| $=====$ | $====$ |

## 4. COMPUTATION OF NET INCOME PER COMMON SHARE AND PER COMMON SHARE-ASSUMING DILUTION

Effective December 31, 1997, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 128, Earnings Per Share, and the provisions of the Securities and Exchange Commission Staff Accounting Bulletin No. 98 and, accordingly, all prior periods have been restated. Net income per common share is computed using the weighted average number of shares of common stock outstanding. Net income per common share-assuming dilution is computed using the weighted average number of shares of common stock and dilutive common equivalent shares from stock options and preferred stock outstanding. The Company has determined that no incremental shares should be included in the computations of earnings per share and in accordance with Staff Accounting Bulletin No. 98.

In accordance with the disclosure requirements of SFAS No. 128, a reconciliation of the numerator and denominator of net income per common share and net income per common share-assuming dilution is provided as follows (in thousands, except per share amounts):


| Numerator -- Net income per common share and per common share -- assuming dilution |  |  |
| :---: | :---: | :---: |
| Net income | \$ 655 | \$ 185 |
| Denominator-- Net income per common share |  |  |
| Weighted average common stock outstanding | 6,459 | 6,356 |
| Net income per common share | \$ 0.10 | \$ 0.03 |
|  |  |  |
| Denominator -- Net income per common share-assuming dilution <br> Weighted average common stock outstanding |  |  |
| Effect of dilutive securities |  |  |
| Weighted average common stock options | 353 | 284 |
| Total weighted average stock and options outstanding | 6,812 | 6,640 |
| Net income per common share-assuming dilution | \$ 0.10 | \$ 0.03 |

During the three months ended March 31, 1998 and 1997, options to purchase 138,394 and 222,925 shares, respectively, at weighted average exercise prices of $\$ 9.93$ and $\$ 7.91$ per share, respectively, were outstanding, but were not included in the computations of net income per common share-assuming dilution because the exercise price of the related options exceeded the market price of the common shares. These options could dilute earnings per share in future periods.

## 5. ADOPTED ACCOUNTING PRONOUNCEMENTS

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, 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. SFAS No. 130, which is effective for interim periods beginning after December 15, 1997, has been adopted by the Company. However, comprehensive income is insignificant for all periods presented and, accordingly, no additional disclosures have been presented in the accompanying financial statements.

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 for the year ended December 31, 1997 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 MARCH 31, |  |
| :---: | :---: | :---: |
|  | 1998 | 1997 |
| Sales | 100.0\% | 100.0\% |
| Cost of sales | 42.4 | 43.3 |
| Gross profit | 57.6 | 56.7 |
| Operating expenses: |  |  |
| Research and development | 9.3 | 12.7 |
| Sales, general and administrative | 33.6 | 39.9 |
| Total operating expenses | 42.9 | 52.6 |
| Income from operations | 14.7 | 4.1 |
| Other income, net | 2.2 | 4.7 |
| Income before provision for income taxes | 16.9 | 8.8 |
| Provision for income taxes | (5.7) | (3.2) |
| Net income | 11.2\% | 5.6\% |

Sales. Sales increased $77 \%$ to $\$ 5.9$ million for the three months ended March 31, 1998 from $\$ 3.3$ million for the three months ended March 31, 1997. The growth in sales was primarily attributable to increased unit volume as the Company expanded its product offerings and broadened its customer base. Domestic sales of $\$ 3.7$ million accounted for $63 \%$ of sales for the three months ended March 31, 1998 compared to $\$ 1.6$ million or $48 \%$ of sales in the comparable 1997 period. The increase in domestic sales was attributable primarily to sales of the DioLite 532 dermatology laser introduced in the second quarter of 1997 and an increase in domestic sales of most products for ophthalmology. In addition, increased domestic sales result in higher average selling prices as domestic sales are primarily sold by employee sales representatives at higher average selling prices than to the Company's international distributors. International sales of $\$ 2.2$ million in the three months ended March 31, 1998 increased from $\$ 1.7$ million in the comparable 1997 period. The increase in international sales was attributable to sales of the DioLite 532, offset somewhat by a reduction in sales to many Asian countries which were recently impacted by currency devaluations. Lower Asian sales have
been mitigated by product sales in other regions and in the United States. The Company expects revenues from international sales to continue to account for a substantial portion of its sales. The Company expects future growth in sales to be primarily derived from sales of the DioLite 532 and the OcuLight GL. There can be no assurance that future currency fluctuations and other factors discussed above will not have a material adverse effect on the Company's business, financial condition or results of operations.

Gross Profit. The Company's gross profit increased $80 \%$ to $\$ 3.4$ million for the three months ended March 31, 1998 from $\$ 1.9$ million for the three months ended March 31, 1997. Gross profit as a percentage of net sales for the three months ended March 31, 1998 increased to $58 \%$, compared to $57 \%$ for the three months ended March 31, 1997, due primarily to increased domestic sales which are primarily sold by employee sales representatives at higher average selling prices than sales to the Company's international distributors, offset somewhat by lower averge selling prices for the DioLite 532. The Company expects that the percentage of international sales is likely to increase during the remainder of 1998, which would negatively impact average selling prices. In addition, ongoing competitive pressure on the prices of the Company's products may result in a decline in average selling prices. The Company intends to continue its efforts to reduce the cost of components and the costs associated with new product introductions, and 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 $30 \%$ to $\$ 0.5$ million for the three months ended March 31, 1998 from $\$ 0.4$ million for the three months ended March 31, 1997, but decreased as a percentage of net sales to $9 \%$ for the three months ended March 31, 1998 from $13 \%$ for the comparable prior year three-month period. The increase in absolute dollars in research and development expenses during this period was primarily attributable to an increase in personnel as the Company strengthened its product development efforts. The Company expects these expenses for research and development to continue to increase in absolute dollars during the remainder of 1998 in connection with new product development activities.

Sales, General and Administrative. Sales, general and administrative expenses grew by $49 \%$ to $\$ 2.0$ million for the three months ended March 31, 1998 from \$1.3 million for the three months ended March 31, 1997, but decreased as a percentage of net sales to $34 \%$ for the three months ended March 31, 1998 from 40\% for the comparable prior year three-month period. The increase in absolute dollars in sales, general and administrative expenses was primarily due to the hiring of additional sales, marketing and administrative employees to address new opportunities, to support expanding unit volumes and the expenses associated with the OcuLight GL and DioLite 532. Furthermore, the increase in domestic sales caused an associated increase in direct selling expenses. In addition, during the three months ended March 31, 1998, the Company began full scale implementation of a new company-wide enterprise resource planning ("ERP") system and expects the implementation of this system to continue through September of 1998. The Company expects sales, general and administrative expenses to continue to increase during the balance of 1998 to support the increasing unit shipment volumes, additional employees and the implementation of the new ERP system.

Income Taxes. The Company's effective tax rate for the three months ended March 31, 1998 was $34 \%$. 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 the Company's foreign sales corporation.

## LIQUIDITY AND CAPITAL RESOURCES

At March 31, 1998, the Company's primary sources of liquidity included cash and cash equivalents and available-for-sale securities of $\$ 12.7$ million. During the three months ended March 31, 1998, the Company used $\$ 0.5$ million in operating activities. Sources of cash included net income of $\$ 0.7$ million, depreciation of
\$0.2 million and increases in accounts payable of $\$ 0.2$ million, offset by increases in accounts receivables of $\$ 1.0$ million and inventories of $\$ 0.5$ million. The increase in inventory is primarily due to increased finished goods inventory. The Company generated $\$ 0.7$ million in investing activities during the three months ended March 31, 1998, primarily from the sales of $\$ 1.0$ million of available-for-sale securities offset by the acquisition of $\$ 0.4$ million of property and equipment. Net cash provided by financing activities during the three months ended March 31, 1998 was $\$ 0.1$ million, which consisted primarily of issuance of stock. 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.

## RECENT ACCOUNTING PRONOUNCEMENTS

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.

## FACTORS THAT MAY AFFECT FUTURE RESULTS

CONTINUED MARKET ACCEPTANCE OF THE COMPANY'S PRODUCTS. The Company currently markets visible and invisible light semiconductor-based photocoagulator medical laser systems to the ophthalmic market and a visible light semiconductor-based photocoagulator medical laser system to the dermatological market. The Company believes that continued and increased sales, if any, of these medical laser systems is dependent upon the continued market acceptance of these products. Medical equipment purchasing decisions and continued market acceptance of the Company's products may in turn depend on opinions of medical professionals, performance and price, product and treatment familiarity, procedure reimbursement economics and other factors. The Company believes that recommendations by ophthalmologists and dermatologists as to the use of semiconductor-based laser systems is essential for the continued market acceptance of the Company's products. Such medical professionals may not recommend these laser systems or related treatments unless they conclude, based on clinical data and other factors, that the performance of these laser systems and treatments are a beneficial alternative to competing technologies and treatments. Favorable recommendations from such medical professionals is particularly important to the Company because the ophthalmic and dermatological communities historically have used more established visible light, argon gas or other ion-based photocoagulation laser systems. The Company's semiconductor-based laser systems are relatively new to the marketplace. The Company's infrared laser systems deliver invisible light to provide additional and, in some instances, improved treatments. Because many ophthalmologists and dermatologists have been trained in medical school using visible argon gas or other ion-based laser systems, they may be reluctant or unwilling to convert to semiconductor-based or infrared laser systems. In addition, ophthalmic procedures are typically reimbursed by third party payers who are increasingly scrutinizing the level of reimbursement for treatment procedures. Furthermore, changes in government legislation or regulation could effect reimbursement levels. A reduction in the level of reimbursement for treatments administered with the Company's ophthalmic products would negatively impact the saleability of such products. Dermatological procedures are typically paid for by the treated patient. Any reduction in the perceived value of such treatments would reduce the price level that dermatologists can charge and would negatively impact the saleability of such products. There can be no assurance that the Company's medical laser systems will continue to be accepted by the market. The failure of medical professionals to recommend the Company's laser systems, the introduction of improved alternative
technologies or treatments, the reluctance or unwillingness of ophthalmologists or dermatologists to convert to semiconductor-based laser systems or to infrared laser systems, or reductions in treatment reimbursements would negatively impact the market acceptance of the Company's products. Any significant decline in market acceptance of the Company's products would have a material adverse effect on the Company's business, results of operations and financial condition.

COMPETITION. Competition in the market for devices used for ophthalmic and dermatological treatments is intense and may 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 other companies that manufacture photocoagulators, the Company's products compete with pharmaceutical treatments, other technologies and other surgical techniques. The Company's principal competitors in ophthalmology are Coherent, Inc., Nidek, Inc. ("Nidek"), Carl Zeiss, Inc. ("Zeiss"), Alcon International ("Alcon"), Keeler Instruments, Inc. ("Keeler") and HGM Medical Laser Systems, Inc. ("HGM"). Of these companies, Nidek, Zeiss, Alcon and Keeler currently offer a semiconductor-based laser system in ophthalmology, and other companies may introduce a semiconductor-based laser system. The Company's principal competitors in dermatology are Laserscope and HGM, neither of which currently offers a semiconductor-based laser system in dermatology. Other competitors have substantially greater financial, engineering, product development, manufacturing, marketing and technical resources than the Company. Such companies may 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 and dermatological conditions targeted by the Company or are less expensive than the Company's current or future products. Moreover, there can be no assurance 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.

RISKS OF MANUFACTURING AND DEPENDENCE ON KEY MANUFACTURERS AND SUPPLIERS. The manufacture of the Company's infrared and visible light semiconductor-based photocoagulator medical laser systems and the related delivery devices is a highly complex and precise process which requires the integration of components with unique characteristics. Accordingly, problems may occur in the manufacture of the Company's products which could prevent shipping of some products or could 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. There can be no assurance that the Company will be able to continue to manufacture its existing products or future products on a cost-effective and timely basis. Although the Company assembles critical subassemblies as well as the final product at its facility in Mountain View, California, the Company relies on third parties to manufacture substantially all of the components used in its products. There are risks associated with the use of independent manufacturers, 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. However, certain of the Company's products remain significantly dependent on sole source suppliers. Certain diodes purchased from SDL, Inc. ("SDL") were not readily available from other suppliers until the second quarter of 1997. During 1996 and the first quarter of 1997, the Company experienced delays in its manufacturing of the OcuLight GL because of 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 recur. During the first quarter of 1997, the Company qualified Opto Power as a second source of this diode component. Because laser diode components are extremely complex and difficult to manufacture, there can be no assurance that the Company's suppliers of such components will be able to timely deliver components in sufficient quantities to meet the Company's requirements. Similar
manufacturing issues or delays in the delivery of other key components of the Company's products could also have a material adverse impact on the Company. 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 inability to obtain components as required at a reasonable cost, or at all, would have a material adverse affect 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 1997 and 1996, the Company's international sales were $\$ 9.4$ million and $\$ 6.1$ million, representing $52 \%$ and $50 \%$, respectively, of total sales. In addition, for the three months ended March 31, 1998 and 1997, the Company's international sales were $\$ 2.2$ million and $\$ 1.7$ million, representing $37 \%$ and $52 \%$ respectively, of total sales. 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. The recent currency devaluation in many Asian countries has had the effect of significantly increasing the purchase price of the Company's products to the Company's distributors and their customers in that region. Conversely, because certain of the Company's competitors are based in Asia, the currency devaluations may put additional downward pressures on the average selling prices of the Company's products. Product sales were lower for the affected Asian region during the first quarter of 1998 and the fourth quarter of 1997 primarily as a result of the currency problem. The Company expects lower sales to the Asian region to continue into 1998. The Company also expects revenues from international sales to continue to account for a substantial portion of its sales. Accordingly, if the Asian economic difficulties are prolonged, worsen or otherwise negatively impact the saleability of the Company's product, these difficulties could negatively impact the Company's business, results of operations, and financial condition. While these currency factors and other factors listed above have been mitigated by product sales in other regions and in the United States, there can be no assurance that future currency fluctuations or other factors discussed above will not have a material adverse effect on the Company's business, financial condition or results of operations.

QUARTERLY FLUCTUATIONS IN OPERATING RESULTS. Although the Company has been profitable on an annual and quarterly basis for the last five 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'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, such as the recent currency devaluation in Asia, and resulting changes in customers' or potential customers' budgets and increased product development costs. For example, the Company's gross profits as a percentage of sales have generally declined in part as a result of increased competition which have led to decreases in average selling prices, particularly with respect to the Company's older products. 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 often decline slightly prior to the meeting of the American Academy of Ophthalmology in the fourth quarter of the year. 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 1997 and decreased during the three months ending March 31, 1998, 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'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.

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, dermatological or other markets. 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.

MANAGEMENT OF GROWTH. With the introduction of new products, 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 is in the process of implementing a new enterprise resource planning ("ERP") system to run the Company's business transaction processes. The Company expects that the installation and implementation of this new system will continue through the third quarter of 1998. The transition to the ERP system is a highly complex and technical process, and it is not uncommon for companies engaged in such a transition to experience unexpected delays and technical problems. Because the Company's operations are currently dependent on its existing system and will be dependent upon the new system once it comes on line, the failure of the Company to successfully implement the ERP system or difficulties encountered in the changeover to the new system may have a material adverse effect on the Company's business and results of
operations. There can be no assurance that the Company will be able to successfully install and implement the ERP system, and failure to do so or difficulties encountered in the implementation process could have a material adverse effect on the Company's business, results of operations and financial condition. 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 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 ("Miravant"), formerly known as PDT, Inc., a maker of photodynamic drugs, under which the Company and Miravant have collaborated to develop a device that emits a laser beam to activate a photodynamic drug developed by Miravant to achieve a desired therapeutic result in the treatment of age-related macular degeneration. The development, clinical testing and regulatory approval of this new photodynamic system will require three to five 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 may 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.

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. 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. Recently, a company has challenged one of the patents held by Light Solutions Corporation, a wholly-owned subsidiary of IRIDEX. The Company believes that this dispute will be settled without a material adverse effect to the Company's business and financial condition.

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 Food and Drug Administration ("FDA") and by foreign and state governments. Pursuant to the FDA Act and the regulations promulgated thereunder, 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 the Company's expectations due to the longer than expected time period required to obtain FDA premarket clearance. Noncompliance with applicable requirements, including 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 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 and are used to treat extremely delicate eye tissue as well as to treat skin conditions primarily on the face. The Company's products 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 products, the Company believes that certain customers may nevertheless reuse these disposable products. Were such a disposable product 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 $\$ 6.0$ million per occurrence and an annual aggregate maximum of $\$ 7.0$ 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.

YEAR 2000 COMPLIANCE. The Company uses a significant number of computer software programs and operating systems in its internal operations, including applications for various financial, business and administrative functions. In addition, many of the Company's suppliers use similar applications. These applications 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. Because there are no internal calendars embedded in any of the Company's products, the Company does not anticipate any problems with its products related to the Year 2000 problem will develop. The Company is currently installing a new ERP system which it believes will be fully Year 2000 compliant. Based on this and other information currently available to the Company, the Company believes that its internal systems currently are, or will be by such time as is necessary to avoid a material adverse impact on the Company, Year 2000 compliant. Also based on information thus far available to the Company, the Company does not believe that it will incur expenditures in dealing with Year 2000 issues that will have a material adverse effect on the financial condition of the Company. In addition to the risks from failure of the Company's own internal systems, the Company may also be exposed to risks from computer systems of parties with whom the Company transacts business. For example, if the internal systems of one of the Company's key suppliers developed problems such that the supplier could not deliver parts to the Company on a timely basis, the Company's financial condition could be materially adversely affected. The Company intends to work with its suppliers to ascertain what actions, if any, are needed. There can be no assurances, however, that unknown costs necessary to update the Company's systems or address potential system interruptions of the Company's or its suppliers' systems will not have a material adverse effect on the Company's business, financial condition or results of operations.
(a) Exhibits
27.1 Financial Data Schedule
(b) Reports on Form 8-K

No reports on Form $8-\mathrm{K}$ have been filed during the period for which this report is filed.
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## 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)

By: /s/ Robert Kamenski
Robert Kamenski
Chief Financial Officer
(Principal Financial and
Principal Accounting Officer)

| EXHIBIT | PAGE |  |
| :--- | :---: | :---: |
| 27.1 | Financial Data Schedule | 20 |

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JAN-01-1998
MAR-31-1998
10,199
2,548
7,357
(285)
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