

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended April 2, 2005

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

For the _____ the _____ Transition _____ period
from _____

Commission File Number: 0-27598

IRIDEX CORPORATION

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

77-0210467

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

1212 Terra Bella Avenue
Mountain View, California 94043-1824
(Address of principal executive offices, including zip code)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes No

APPLICABLE TO CORPORATE ISSUERS:

The number of shares of common stock, \$.01 par value, issued and outstanding as of May 10, 2005 was 7,433,298.

| | | |
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| Exhibit 31.1 | Certification of Chief Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) | |
| Exhibit 31.2 | Certification of Chief Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) | |
| Exhibit 32.1 | Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 | |

Part I. FINANCIAL INFORMATION**Item 1. Condensed Consolidated Financial Statements**

IRIDEX Corporation
Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

| <u>Assets</u> | <u>April 2,</u> <u>2005</u> | <u>January 1,</u> <u>2005</u> |
|--|--------------------------------|----------------------------------|
| Current assets: | | |
| Cash and cash equivalents | \$ 6,202 | \$ 10,381 |
| Available-for-sale securities | 8,907 | 3,323 |
| Accounts receivable, net | 6,848 | 7,404 |
| Inventories | 9,511 | 8,922 |
| Prepays and other current assets | 1,078 | 814 |
| Current deferred income taxes | 1,808 | 1,808 |
| Total current assets | <u>34,354</u> | <u>32,652</u> |
| Long term portion of available-for-sale securities | 1,535 | 4,324 |
| Property and equipment, net | 854 | 852 |
| Deferred income taxes | 1,265 | 1,265 |
| Total assets | <u>\$ 38,008</u> | <u>\$ 39,093</u> |
| Liabilities and Stockholders' Equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 1,179 | \$ 1,233 |
| Accrued expenses | 4,058 | 5,167 |
| Deferred revenue | 962 | 910 |
| Total liabilities | <u>6,199</u> | <u>7,310</u> |
| Stockholders' equity: | | |
| Common stock | 74 | 74 |
| Additional paid-in capital | 25,352 | 25,281 |
| Accumulated other comprehensive loss | (60) | (35) |
| Treasury stock | (430) | (430) |
| Retained earnings | 6,873 | 6,893 |
| Total stockholders' equity | <u>31,809</u> | <u>31,783</u> |
| Total liabilities and stockholders' equity | <u>\$ 38,008</u> | <u>\$ 39,093</u> |

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

IRIDEX Corporation
Condensed Consolidated Statements of Operations
(in thousands, except per share data)
(unaudited)

| | Three Months Ended | |
|---|--------------------|------------------|
| | April 2, 2005 | April 3, 2004 |
| Sales | \$ 8,145 | \$ 7,392 |
| Cost of sales | 4,467 | 4,177 |
| Gross profit | <u>3,678</u> | <u>3,215</u> |
| Operating expenses: | | |
| Research and development | 1,039 | 1,107 |
| Sales, general and administrative | 2,797 | 2,193 |
| Total operating expenses | <u>3,836</u> | <u>3,300</u> |
| Loss from operations | (158) | (85) |
| Interest and other income, net | 126 | 60 |
| Loss before income taxes | (32) | (25) |
| Benefit from income taxes | 12 | 8 |
| Net loss | <u>\$ (20)</u> | <u>\$ (17)</u> |
| Net loss per share - basic and diluted | <u>\$ (0.00)</u> | <u>\$ (0.00)</u> |
| Shares used in computing net loss per share - basic and diluted | <u>7,317</u> | <u>7,076</u> |

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 | |
|---|--------------------|------------------|
| | April 2, 2005 | April 3, 2004 |
| Cash flows from operating activities: | | |
| Net loss | \$ (20) | \$ (17) |
| Adjustments to reconcile net loss to net cash provided by (used in) operating activities: | | |
| Depreciation and amortization | 113 | 137 |
| Provision for inventories | 57 | 11 |
| Provision for doubtful account | (5) | (4) |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 561 | 727 |
| Inventories | (646) | 240 |
| Prepays and other current assets | (264) | (440) |
| Accounts payable | (54) | (321) |
| Accrued expenses | (1,109) | (375) |
| Deferred revenue | 52 | 49 |
| Net cash provided by (used in) operating activities | <u>(1,315)</u> | <u>7</u> |
| Cash flows from investing activities: | | |
| Purchases of available-for-sale securities | (7,151) | (3,539) |
| Proceeds from maturity of available-for-sale securities | 4,331 | 1,845 |
| Acquisition of property and equipment | (115) | (83) |
| Net cash used in investing activities | <u>(2,935)</u> | <u>(1,777)</u> |
| Cash flows from financing activities: | | |
| Issuance of common stock | 71 | 706 |
| Net cash provided by financing activities | <u>71</u> | <u>706</u> |
| Net decrease in cash and cash equivalents | (4,179) | (1,064) |
| Cash and cash equivalents at beginning of period | <u>10,381</u> | <u>10,541</u> |
| Cash and cash equivalents at end of period | <u>\$ 6,202</u> | <u>\$ 9,477</u> |

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

IRIDEX Corporation
Condensed Consolidated Statements of Comprehensive Loss
(in thousands)
(unaudited)

| | Three Months Ended | |
|---|--------------------|------------------|
| | April 2, 2005 | April 3, 2004 |
| Net loss | \$ (20) | \$ (17) |
| Other comprehensive loss: | | |
| Change in unrealized loss on available-for-sale securities, net of tax | (16) | (5) |
| Comprehensive loss | <u>\$ (36)</u> | <u>\$ (22)</u> |

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

IRIDEX Corporation
Notes to Unaudited Condensed Consolidated Financial Statements

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of IRIDEX Corporation ("the Company") have been prepared in accordance with generally accepted accounting principles in the United States of America for interim financial information and pursuant to the instructions to Form 10-Q and Article 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring adjustments, considered necessary for a fair statement of the financial statements have been included.

The condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto, together with management's discussion and analysis of financial condition and results of operations, contained in our Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission on April 1, 2005. The results of operations for the three month period ended April 2, 2005 are not necessarily indicative of the results for the year ending December 31, 2005 or any future interim period.

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are disclosed in our Annual Report on Form 10-K for the year ended January 1, 2005 which was filed with the Securities and Exchange Commission on April 1, 2005. The Company's significant accounting policies have not materially changed as of April 2, 2005.

Deferred Revenue

Deferred revenue related to warranty contracts is recognized on a straight line basis over the period of the applicable contract. Cost is recognized as incurred. A reconciliation of changes in the Company's deferred revenue balances for the three months ending April 2, 2005 and April 3, 2004 follows (in thousands):

| | Three Months Ended | |
|------------------------------|--------------------|---------------|
| | April 2, 2005 | April 3, 2004 |
| Balance, beginning of period | \$ 910 | \$ 596 |
| Additions to deferral | 397 | 223 |
| Revenue recognized | (345) | (174) |
| Balance, end of period | <u>\$ 962</u> | <u>\$ 645</u> |

Warranty

The Company accrues for an estimated warranty cost upon shipment of products in accordance with Statement of Financial Accounting Standards (“SFAS”) No. 5, “Accounting for Contingencies.” Actual warranty costs incurred have not materially differed from those accrued. The Company’s warranty policy is effective for shipped products which are considered defective or fail to meet the product specifications. Warranty costs are reflected in the statement of operations as a cost of sales. A reconciliation of the changes in the Company’s warranty liability for the three months ending April 2, 2005 and April 3, 2004 follows (in thousands):

| | Three Months Ended | |
|--|--------------------|---------------|
| | April 2, 2005 | April 3, 2004 |
| Balance, beginning of period | \$ 933 | \$ 801 |
| Accruals for warranties issued during the period | 167 | 182 |
| Settlements made in kind during the period | (144) | (138) |
| Balance, end of period | <u>\$ 956</u> | <u>\$ 845</u> |

Accounting for Stock-Based Compensation

The Company accounts for stock-based compensation arrangements in accordance with provisions of Accounting Principles Board Opinion (“APB”) No. 25, “Accounting for Stock Issued to Employees” and complies with the disclosure provisions of SFAS No. 123, “Accounting for Stock-Based Compensation,” as amended by SFAS No. 148, “Accounting for Stock-Based Compensation - Transition and Disclosure - an Amendment of FASB Statement No. 123.”

Under APB 25, compensation expense for stock option grants to employees is based on the difference, if any, on the date of the grant, between the fair value of the Company’s stock and the option’s exercise price. SFAS 123 defines a “fair value” based method of accounting for an employee stock option or similar equity investment. The pro forma disclosure of the difference between compensation expense included in net loss and the related cost measured by the fair value method is presented below.

The following table provides a reconciliation of net loss to pro forma net loss as if the fair value method had been applied to all employee awards (in thousands, except per share data):

| | Three Months Ended | |
|---|--------------------|-----------------|
| | April 2, 2005 | April 3, 2004 |
| Net loss, as reported | \$ (20) | \$ (17) |
| Add: Total stock based compensation expense, net of tax, determined under fair value based method for all awards to employees | (125) | (144) |
| Pro forma net loss | <u>\$ (145)</u> | <u>\$ (161)</u> |
| Basic and diluted net loss per share: | | |
| As reported | \$ (0.00) | (\$0.00) |
| Pro forma | <u>\$ (0.02)</u> | <u>(\$0.02)</u> |

The determination of fair value of all options granted by the Company is computed based on the following assumptions:

| | Employee Stock Option Plan | | Employee Stock Purchase Plan | |
|---------------------------------|----------------------------|---------------|------------------------------|---------------|
| | Three Months Ended | | Three Months Ended | |
| | April 2, 2005 | April 3, 2004 | April 2, 2005 | April 3, 2004 |
| Average risk free interest rate | 3.38% | 1.88% | 2.50% | 1.00% |
| Expected life (in years) | 3 yrs | 2 yrs. | 0.5 yrs | 0.5 yrs. |
| Dividend yield | -- | -- | -- | -- |
| Average volatility | 86.0% | 87.0% | 85.0% | 87.0% |

3. Inventories

Inventories are stated at the lower of cost or market. Cost is based on actual sales computed on a first in, first out basis. The components of inventories consist of the following (in thousands):

| | April 2, 2005 | | January 2, 2005 | |
|------------------------------------|------------------|--------------|--------------------|--------------|
| Raw materials and work in progress | \$ | 5,405 | \$ | 5,460 |
| Finished goods | | 4,106 | | 3,462 |
| Total inventories | \$ | 9,511 | \$ | 8,922 |

4. Computations of Net Loss Per Common Share

Basic and diluted net loss per share are computed by dividing net loss for the period by the weighted average number of shares of common stock outstanding during the period. The calculation of diluted net loss per share includes the dilutive effect of potentially dilutive common stock provided the inclusion of such potential common stock is not antidilutive. Potentially dilutive common stock consists of incremental common shares issuable upon the exercise of stock options.

During the three months ended April 2, 2005, options to purchase 1,898,249 shares of common stock at a weighted average exercise price of \$5.33 per share and approximately 10,276 shares issuable to our employee stock purchase plan were outstanding, but were not included in the computations of diluted net loss per common share because their effect was antidilutive. During the three months ended April 3, 2004, options to purchase 1,853,016 shares at a weighted average exercise price of \$5.44 and 16,713 shares issuable to our employee stock purchase plan were outstanding, but were not included in the computations of diluted net loss per share because their effect was antidilutive. These options could dilute earnings per share in future periods.

5. Business Segments

We operate in two reportable segments: the ophthalmology medical device segment and the dermatology medical device segment. In both segments, we develop, manufacture and market medical devices. Our revenues arise from the sale of consoles, delivery devices, disposables and service and support activities.

Information on reportable segments for the three months ended April 2, 2005 and April 3, 2004 is as follows (in thousands):

| | Three Months Ended April 2, 2005 | | | Three Months Ended April 3, 2004 | | |
|---------------------------|-------------------------------------|-----------------------------------|----------|-------------------------------------|-----------------------------------|----------|
| | Ophthalmology Medical Devices | Dermatology Medical Devices | Total | Ophthalmology Medical Devices | Dermatology Medical Devices | Total |
| Sales | \$ 6,193 | \$ 1,952 | \$ 8,145 | \$ 6,243 | \$ 1,149 | \$ 7,392 |
| Direct Cost of Goods Sold | 2,099 | 996 | 3,095 | 2,241 | 648 | 2,889 |
| Direct Gross Margin | 4,094 | 956 | 5,050 | 4,002 | 501 | 4,503 |
| Total Unallocated Costs | | | (5,082) | | | (4,528) |
| Pre-tax loss | | | \$ (32) | | | \$ (25) |

Indirect costs of manufacturing, research and development, and selling, general and administrative costs are not allocated to the segments.

The Company's assets and liabilities are not evaluated on a segment basis. Accordingly, no disclosure of segment assets and liabilities is provided.

6. Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board ("FASB") issued ("SFAS") No. 123 (R), "Share-Based Payments" (revised 2004). The provisions of SFAS 123 (R) will require the Company to measure all stock-based compensation awards using a fair value method and record such expense in the consolidated financial statements, including grants of employee stock options. In addition, the adoption of SFAS 123(R) will require additional accounting related to the income tax effects and additional disclosure regarding the cash flow effects resulting from share-based payment arrangements. SFAS 123 (R) is effective for all public companies for fiscal years beginning after June 15, 2005. The Company will adopt SFAS 123 (R) effective January 1, 2006. The Company has not yet determined whether the adoption of FAS 123(R) will result in amounts that are similar to the current pro forma disclosures under SFAS 123. The Company is evaluating the requirements for FAS 123 (R) and expects the adoption to have a significant adverse impact on the statement of operations and net loss per share.

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

This Quarterly Report on Form 10-Q contains trend analysis and other forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, such as statements relating to levels of future sales and operating results, actual order rate and market acceptance of our products; expectations for future sales growth, generally, including expectations of additional sales from our new products and new applications of our existing products; the potential for production cost decreases and higher gross margins; our ability to develop and introduce new products through strategic alliances; favorable Center for Medicare and Medicaid coverage decisions regarding procedures that use our products; results of clinical studies and risks associated with bringing new products to market; general economic conditions; levels of international sales; determinations regarding deferred tax assets; and the sufficiency of our cash, cash equivalents and available-for-sale securities together with cash generated from operations and our credit facility to meet our anticipated cash requirements for the next 12 months. In some cases, forward-looking statements can be identified by terminology, such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "intends," "potential," "continue," or the negative of such terms or other comparable terminology. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to differ materially from those expressed or implied by such forward-looking statements, including as a result of the factors set forth under "Factors That May Affect Future Operating Results" below. The reader is cautioned not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this Form 10-Q. We undertake no obligation to update such forward-looking statements to reflect events or circumstances occurring after the date of this report.

Results of Operations

The following table sets forth certain operating data as a percentage of sales for the periods indicated.

| | Three Months Ended | |
|-----------------------------------|--------------------|------------------|
| | April 2, 2005 | April 3, 2004 |
| Sales | 100.0% | 100.0% |
| Cost of sales | 54.8 | 56.5 |
| Gross profit | 45.2 | 43.5 |
| Operating expenses: | | |
| Research and development | 12.8 | 15.0 |
| Sales, general and administrative | 34.3 | 29.6 |
| Total operating expenses | 47.1 | 44.6 |
| Loss from operations | (1.9) | (1.1) |
| Interest and other income, net | 1.5 | 0.8 |
| Loss before income taxes | (0.4) | (0.3) |
| Benefit from income taxes | 0.2 | 0.1 |
| Net loss | (0.2)% | (0.2)% |

The following table sets forth for the periods indicated the amount of sales for our operating segments and sales as a percentage of total sales.

| | Three Months Ended | | | |
|-----------------------|--------------------|---------------------------|-----------------|---------------------------|
| | April 2, 2005 | | April 3, 2004 | |
| | Amount | Percentage of total sales | Amount | Percentage of total sales |
| Domestic | \$ 4,925 | 60.5% | \$ 4,156 | 56.2% |
| International | 3,220 | 39.5% | 3,236 | 43.8% |
| Total | \$ 8,145 | 100.0% | \$ 7,392 | 100.0% |
| Ophthalmology: | | | | |
| Domestic | \$ 3,413 | 41.9% | \$ 3,366 | 45.5% |
| International | 2,780 | 34.1% | 2,877 | 38.9% |
| Total | \$ 6,193 | 76.0% | \$ 6,243 | 84.4% |
| Dermatology: | | | | |
| Domestic | \$ 1,512 | 18.6% | \$ 790 | 10.7% |
| International | 440 | 5.4% | 359 | 4.9% |
| Total | \$ 1,952 | 24.0% | \$ 1,149 | 15.6% |

Ophthalmology Sales

Ophthalmology sales of \$6.2 million remained relatively constant for the three month periods ending April 2, 2005 and April 3, 2004. For the three month period ended April 2, 2005 and April 3, 2004, domestic ophthalmology sales remained relatively level at \$3.4 million. Likewise, within domestic ophthalmology, the dollar mix of laser consoles and delivery devices were both relatively constant for this time period. International ophthalmology sales decreased 3.4% to \$2.8 million for the three months ended April 2, 2005 from \$2.9 million for the three months ended April 3, 2004. The decrease in international ophthalmology sales during this period was due to a \$0.1 million decrease in unit sales of ophthalmology laser consoles, while sales of laser delivery devices remained relatively level.

Dermatology Sales

Dermatology sales increased 69.8% to \$2.0 million for the three months ended April 2, 2005 from \$1.1 million for the three months ended April 3, 2004. Domestic dermatology sales increased 91.4% to \$1.5 million for the three month period ended April 2, 2005 from \$0.8 million for the comparable three month period in 2004 due primarily to unit sales of the new VariLite laser system. International dermatology sales increased 22.6% to \$0.4 million for the three months ended April 2, 2005 from \$0.36 million for the three months ended April 3, 2004 due primarily to unit sales of the new VariLite laser system.

Gross Profit. Our gross profit increased by \$0.5 million to \$3.7 million for the three month period ended April 2, 2005 compared to \$3.2 million for the three months ended April 3, 2004. Gross profit as a percentage of sales for the three months ended April 2, 2005 increased to 45.2% from 43.5% for the comparable prior year three month period. The total 1.7% increase in gross profit as a percentage of sales during this period resulted primarily from 3.1% due to reduced overhead spending, offset by 1.2% for increased product costs including inventory and warranty reserves and 0.2% due to decreased average selling prices. Although increasing competition has continued to result in a downward trend in average selling prices for some products, we intend to continue our efforts to reduce the cost of components and manufacturing and thereby mitigate the impact of price reductions on our gross profit. In addition, as we evaluate gross margins on each of our product lines, we may choose to place greater focus on product lines with better margins. See “Factors That May Affect Future Results - If We Cannot Increase Our Sales Volumes, Reduce Our Costs or Introduce Higher Margin Products to Offset Anticipated Reductions in the Average Unit Selling Price of our Products, Our Operating Results May Suffer.” We expect our gross profit margins to continue to fluctuate due to changes in the relative proportions of domestic and international sales, mix of sales of existing products, pricing, product costs and a variety of other factors. See “Factors That May Affect Future Results - Our Operating Results May Fluctuate from Quarter to Quarter and Year to Year.”

Research and Development. Our research and development expenses decreased by 6.1% to \$1.03 million for the three months ended April 2, 2005 from \$1.1 million for the three months ended April 3, 2004. Research and development expenses decreased as a percentage of sales to 12.8% for the three months ended April 2, 2005 from 15.0% for the comparable prior year three month period. The decrease in research and development expense in absolute dollars and as a percentage of sales for the three month period ended April 2, 2005 was due primarily to \$0.07 million in decreased research and development project spending. Overall, we expect the level of research and development spending for fiscal year 2005 in absolute dollars to be roughly equivalent to fiscal year 2004.

Sales, General and Administrative. Our sales, general and administrative expenses increased by 27.5% to \$2.8 million for the three months ended April 2, 2005 from \$2.2 million for the three months ended April 3, 2004. As a percentage of sales, sales, general and administrative expenses increased to 34.3% for the three months ended April 2, 2005 from 29.6% for the comparable prior year three month period. The increase in sales, general and administrative expense in absolute dollars and as a percentage of sales for the three month period ended April 2, 2005 was due primarily to a \$0.2 million increase in selling costs related to increased headcount, \$0.1 million due to increased marketing spending and \$0.3 million in general and administrative spending related to increased consulting fees, public company costs and legal fees. For fiscal year 2005, we expect the level of sales, general and administrative spending in absolute dollars to exceed that of fiscal 2004 primarily due to increased sales expense associated with the hiring of additional dermatology headcount, public company expenses, costs associated with hiring and perhaps relocating a new Chief Executive Officer for the Company and marketing expenses associated with recently introduced products.

Interest and Other Income, net. For the three months ended April 2, 2005, we had net other income of \$126,000 as compared with net other income of \$60,000 for the three months ended April 3, 2004. The change in net other income for the three month period was due primarily to an increase in interest income associated with increased cash, cash equivalents and available for sale securities.

Income Taxes. The effective income tax rates for the three month periods ended April 2, 2005 and April 3, 2004 were lower for periods where we had pre-tax income and higher for periods where we had pre-tax losses than the Federal and State combined statutory rate of 40% primarily because of certain tax benefits associated with tax credits for research and development activities. Since the Company was almost at breakeven for the quarter, this tax rate may be adjusted in future quarters.

In addition to estimating our quarterly income tax benefit we assess temporary differences resulting from differing treatment of items for tax and accounting purposes which result in deferred tax assets and liabilities, which are included in our balance sheet. Currently, we have determined that no valuation allowance is required against our deferred tax assets as it is more likely than not that the deferred tax assets can be realized based on determination of our future taxable income. A valuation allowance is required to reduce our deferred tax assets to the amount that is more likely than not to be realized. However, if at any point in time, we determine that it is more likely than not that we will not realize all or a portion of our remaining deferred tax assets, we will increase our valuation allowance with a charge to income tax expense. Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. In the event that actual results differ from these estimates or we adjust these estimates in future periods, we may need to establish a valuation allowance which could materially impact our financial position and results of operations. Our ability to utilize our deferred tax assets and the continuing need for a related valuation allowance are monitored on an ongoing basis.

Liquidity and Capital Resources

At April 2, 2005, our primary sources of liquidity included cash and cash equivalents and available-for-sale securities in the aggregate amount of \$16.6 million. In addition, we have available \$4 million under our unsecured line of credit which bears interest at the bank's prime rate and expires in October 2006. As of April 2, 2005, no borrowings were outstanding under this credit facility.

During the three months ended April 2, 2005, operating activities used \$1.3 million of cash. The primary uses of cash from operating activities included a decrease in accrued expenses of \$1.1 million, an increase in net inventory of \$0.6 million and an increase of \$0.3 million in prepaid expenses offset by sources of cash which primarily included a \$0.6 million decrease in accounts receivable and depreciation of \$0.1 million. The decrease in accrued expenses resulted primarily from payment of an accrual for a sales tax liability. The accrual for sales tax represented a reserve resulting from the completion of a comprehensive review of our sales tax practices. Historically, we had been collecting and remitting sales tax in only those states where we believed we had nexus. Based on the independent review, we are now collecting and remitting sales tax from customers in additional states and have entered into voluntary settlement agreements with certain states. The Company chose not to retroactively collect this sales tax from our customers. The increase in inventory related primarily to purchases connected with the Company's recent introduction of new products.

Investing activities used \$2.9 million in cash and cash equivalents during the three months ended April 2, 2005, primarily due to net purchases of available for sale securities of \$2.8 million and purchases of fixed assets of \$0.1 million.

Net cash provided by financing activities during the three months ended April 2, 2005 was \$0.1 million which consisted of the issuance of common stock under employee option plans and the employee stock purchase plan.

We believe that, based on current estimates, our cash, cash equivalents and available-for-sale securities together with cash generated from operations and our credit facility will be sufficient to meet our anticipated cash requirements for the next 12 months. Our liquidity could be negatively affected by a decline in demand for our products, the need to invest in new product development or reductions in spending by our customers as a result of the continuing economic downturn or other factors. There can be no assurance that additional debt or equity financing will be available when required or, if available, can be secured on terms satisfactory to us. See "Factors That May Affect Future Results - We May Need Additional Capital, which May Not Be Available, and Our Ability to Grow May Be Limited as a Result."

In December 1998, we instituted a stock repurchase program whereby up to 150,000 shares of our common stock may be repurchased in the open market. We plan to utilize all of the reacquired shares for reissuance in connection with employee stock programs. No shares were repurchased during the three months ended April 2, 2005. To date, we have purchased 103,000 shares of our common stock under this program.

Critical Accounting Policies

The Company's significant accounting policies are disclosed in our Annual Report on Form 10-K for the year ended January 1, 2005 which was filed with the Securities and Exchange Commission on April 2, 2005.

Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board ("FASB") issued ("SFAS") No. 123 (R), "Share-Based Payments" (revised 2004). The provisions of SFAS 123 (R) will require the Company to measure all stock-based compensation awards using a fair value method and record such expense in the consolidated financial statements, including grants of employee stock options. In addition, the adoption of SFAS 123(R) will require additional accounting related to the income tax effects and additional disclosure regarding the cash flow effects resulting from share-based payment arrangements. SFAS 123 (R) is effective for all public companies for fiscal years beginning after June 15, 2005. The Company will adopt SFAS 123 (R) effective January 1, 2006. The Company has not yet determined whether the adoption of FAS 123(R) will result in amounts that are similar to the current pro forma disclosures under SFAS 123. The Company is evaluating the requirements for FAS 123 (R) and expects the adoption to have a significant adverse impact on the statement of operations and net loss per share.

Factors That May Affect Future Results

We Rely on Continued Market Acceptance of Our Existing Products and Any Decline in Sales of Our Existing Products Would Adversely Affect Our Business and Results of Operations. We currently market visible and infrared light semiconductor-based photocoagulator medical laser systems to the ophthalmic market. We also market visible and infrared light semiconductor-based photocoagulator medical laser systems to the dermatology market. We believe that continued and increased sales, if any, of these medical laser systems is dependent upon a number of factors including the following:

- § Product performance, features, ease of use, scalability and durability;
- § Recommendations and opinions by ophthalmologists, dermatologists, other clinicians, plastic surgeons and their associated opinion leaders, including study outcomes;
- § Price of our products and prices of competing products and technologies;
- § Availability of competing products, technologies and alternative treatments;
- § Willingness of ophthalmologists and dermatologists to convert to semiconductor-based or infrared laser systems from alternative technologies; and
- § Level of reimbursement for treatments administered with our products.

In addition, we derive a meaningful portion of our revenues from the sale of delivery devices. Our ability to increase revenues from the sale of delivery devices will depend primarily upon the features, ease of use and prices of our products, including the relationship to prices of competing delivery devices. The level of service revenues will depend on our quality of care, responsiveness and the willingness of our customers to request our services rather than purchase competing products or services. Any significant decline in market acceptance of our products or our revenues derived from the sales of laser consoles, delivery devices or services would have a material adverse effect on our business, results of operations and financial condition.

We Face Strong Competition in Our Markets and Expect the Level of Competition to Grow in the Foreseeable Future. Competition in the market for devices used for ophthalmic and dermatology treatment procedures is intense and is expected to increase. Our competitive position depends on a number of factors including product performance, characteristics and functionality, ease of use, scalability, durability and cost. Our principal competitors in ophthalmology are Lumenis Ltd., Carl Zeiss, Inc., Alcon, Quantel, Laserex and Nidek, Inc. All of these companies currently offer a competitive semiconductor-based laser system in ophthalmology. Also within ophthalmology pharmaceutical alternative treatments for AMD such as Visudyne (Novartis) and Macugen (Eyeteck) compete rigorously with traditional laser procedures. Our principal competitors in dermatology are Laserscope, Candela Corporation, Palomar Technologies, Lumenis Ltd. and Cutera, Inc. Some competitors have substantially greater financial, engineering, product development, manufacturing, marketing and technical resources than we do. Some companies also have greater name recognition than we do and long-standing customer relationships. In addition to other companies that manufacture photocoagulators, we compete with pharmaceuticals, other technologies and other surgical techniques. Some medical companies, academic and research institutions, or others, may develop new technologies or therapies that are more effective in treating conditions targeted by us or are less expensive than our current or future products. Any such developments could have a material adverse effect on our business, financial condition and results of operations.

Our Future Success Depends on Our Ability to Develop and Successfully Introduce New Products and New Applications. Our future success is dependent upon, among other factors, our ability to develop, obtain regulatory approval or clearance of, manufacture and market new products. In October 2004, we introduced two new laser products, the IQ810 in ophthalmology and the VariLite in dermatology. In May 2004, we introduced a new type of illuminating Endoprobe. In June 2003 we began shipment of two new products; a 50 micron slit lamp adaptor and a 25 gauge single-use Endoprobe. In October 2002, we announced the introduction of a number of new products, specifically the OcuLight Symphony multi-wavelength laser delivery system, an expanded EndoProbe product line and a 5 mm Large Spot Slit Lamp Adapter. We also announced the Millennium Endolase module in 2002, which we manufacture to be included in Bausch & Lomb's Millennium Microsurgical System. Successful commercialization of these and other new products and new applications will require that we effectively transfer production processes from research and development to manufacturing and effectively coordinate with our suppliers. In addition, we must successfully sell and achieve market acceptance of new products and applications and enhanced versions of existing products. The extent of, and rate at which, market acceptance and penetration are achieved by future products is a function of many variables, which include, among other things, price, safety, efficacy, reliability, marketing and sales efforts, the development of new applications for these products, the availability of third-party reimbursement of procedures using our new products, the existence of competing products and general economic conditions affecting purchasing patterns. Our ability to market and sell new products may also be subject to government regulation, including approval or clearance by the United States Food and Drug Administration, or FDA, and foreign government agencies. Any failure in our ability to successfully develop and introduce new products or enhanced versions of existing products and achieve market acceptance of new products and new applications could have a material adverse effect on our operating results and would cause our net revenues to decline.

If We Cannot Increase Our Sales Volumes, Reduce Our Costs or Introduce Higher Margin Products to Offset Anticipated Reductions in the Average Unit Price of Our Products, Our Operating Results May Suffer. We have experienced declines in the average unit price of our products and expect to continue to suffer from declines in the future. The average unit price of our products may decrease in the future in response to changes in product mix, competitive pricing pressures, new product introductions by our competitors or other factors. If we are unable to offset the anticipated decrease in our average selling prices by increasing our sales volumes or through new product introductions, our net revenues will decline. In addition, to maintain our gross margins, we must continue to reduce the manufacturing cost of our products. If we cannot maintain our gross margins, our business could be seriously harmed, particularly if the average selling price of our products decreases significantly without a corresponding increase in sales.

We Depend on Sales of Our Ophthalmology Products for a Significant Portion of Our Operating Results. We derive, and expect to continue to derive, a large portion of our revenue and profits from sales of our ophthalmology products. For the three months ended April 2, 2005 our ophthalmology sales were \$6.2 million or 76.0% of total sales. We anticipate that sales of our ophthalmology products will continue to account for a significant portion of our revenues in the foreseeable future as we continue to introduce new ophthalmology products, such as the IQ810 Laser System.

We Depend on International Sales for a Significant Portion of Our Operating Results. We derive, and expect to continue to derive, a large portion of our revenue from international sales. For the three months ended April 2, 2005, our international sales were \$3.2 million or 39.5% of total sales. We anticipate that international sales will continue to account for a significant portion of our revenues in the foreseeable future. None of our international revenues and costs has been denominated in foreign currencies. As a result, an increase in the value of the U.S. dollar relative to foreign currencies makes our products more expensive and thus less competitive in foreign markets. The factors stated above could have a material adverse effect on our business, financial condition or results of operations. Our international operations and sales are subject to a number of other risks including:

- § Longer accounts receivable collection periods;
- § Impact of recessions in economies outside of the United States;
- § Foreign certification requirements, including continued ability to use the “CE” mark in Europe;
- § Reduced or limited protections of intellectual property rights in jurisdictions outside the United States;
- § Potentially adverse tax consequences; and
- § Multiple protectionist, adverse and changing foreign governmental laws and regulations.

Any one or more of these factors stated above could have a material adverse effect on our business, financial condition or results of operations. For additional discussion about our foreign currency risks, see Item 3, “Quantitative and Qualitative Disclosures about Market Risk.”

We Rely on Our Direct Sales Force and Network of International Distributors to Sell Our Products and any Failure to Maintain Our Direct Sales Force and Distributor Relationships Could Harm Our Business. Our ability to sell our products and generate revenue depends upon our direct sales force within the United States and relationships with independent distributors outside the United States. As of April 2, 2005 our direct sales force consisted of 14 employees with 3 additional open positions and we maintained relationships with 73 independent distributors internationally selling our products into 107 countries. We generally grant our distributors exclusive territories for the sale of our products in specified countries. The amount and timing of resources dedicated by our distributors to the sales of our products is not within our control. Our international sales are entirely dependent on the efforts of these third parties. If any distributor breaches or fails to generate sales of our products, we may be forced to replace the distributor and our ability to sell our products into that exclusive sales territory would be adversely affected.

We do not have any long-term employment contracts with the members of our direct sales force. We may be unable to replace our direct sales force personnel with individuals of equivalent technical expertise and qualifications or hire qualified personnel to fill any vacant positions in our direct sales force, which may limit our revenues and our ability to maintain market share. The loss of the services of these key personnel would harm our business. Similarly, our distributorship agreements are generally terminable at will by either party and distributors may terminate their relationships with us, which would affect our international sales and results of operations.

We are Dependent on the Successful Outcome of Clinical Trials of Our Products and New Applications Using Our Products. Our success will depend in part on the successful outcome of clinical trials of our products and new applications using our products. Clinical trials are long, expensive and uncertain processes. We have supported several clinical trials, including, for example, the TTT4CNV clinical trial. The TTT4CNV clinical trial is a physician initiated multi-center, prospective, double-masked, placebo-controlled, randomized trial conducted at 22 centers in the United States. This is a clinical trial performed within the FDA cleared indications of the OcuLight SLx and is being conducted to determine whether TTT laser treatment using our OcuLight SLx infrared laser system and Large Spot Slit Lamp Adapter can reduce the risk of vision loss for patients with wet AMD compared to a randomized control, which should reflect the natural history of the disease. In June 2003, we announced the publication of two additional clinical studies, which also support the effectiveness of TTT for the treatment of wet age-related macular degeneration. Both studies were prospective, non-randomized, non-masked case series that were performed using our OcuLight SLx laser and Large Spot Size Slit Lamp Adapter. In October 2004, we announced that the preliminary visual outcome data in the intent-to-treat evaluation showed that TTT, as applied in the TTT4CNV trial, showed favorable trends but overall did not demonstrate a significant beneficial effect relative to sham and that further subgroup analysis would be conducted. Since that time, results of subgroup analysis have demonstrated a statistically significant benefit in a subgroup of patients with baseline visual acuity of 20/100 or worse. Within the TTT4CNV clinical trial, about 41% of the patients enrolled had baseline vision of 20/100 or worse. Specifically, at 12 months following treatment 23% of TTT treated eyes improved vision by one or more lines and 14% of TTT treated eyes improved vision by three or more lines compared with none of the eyes in the placebo treated control group. Furthermore, at 18 months, there was a 2 line benefit in preserving vision in this subgroup when compared to placebo treated eyes. Specifically, TTT treated eyes on average lost 2 lines of visual acuity while placebo treated eyes lost 4 lines. Any impact on laser sales related to these trial results may take a number of years. If the future results of any clinical trial regarding our products fails to demonstrate improved outcomes of treatment using our products, our ability to generate revenues from new products or new applications using our products would be adversely affected.

We Face Manufacturing Risks. The manufacture of our infrared and visible light photocoagulators and the related delivery devices is a highly complex and precise process. We assemble critical subassemblies and all of our final products at our facility in Mountain View, California. We may experience manufacturing difficulties, quality control issues or assembly constraints, particularly with regard to new products that we may introduce. We may not be able to manufacture sufficient quantities of our products, which may require that we qualify other manufacturers for our products. Furthermore, we may experience delays, disruptions, capacity constraints or quality control problems in our manufacturing operations and, as a result, product shipments to our customers could be delayed, which would negatively impact our net revenues.

If We Fail to Accurately Forecast Demand For Our Product and Component Requirements For the Manufacture of Our Product, We Could Incur Additional Costs or Experience Manufacturing Delays and May Experience Lost Sales or Significant Inventory Carrying Costs. We use quarterly and annual forecasts based primarily on our anticipated product orders to plan our manufacturing efforts and determine our requirements for components and materials. It is very important that we accurately predict both the demand for our product and the lead times required to obtain the necessary components and materials. Lead times for components vary significantly and depend on numerous factors, including the specific supplier, the size of the order, contract terms and current market demand for such components. If we overestimate the demand for our product, we may have excess inventory, which would increase our costs. Over the past several quarters, we have placed a high priority on our asset management efforts to, among other things, reduce overall inventory levels and increase our cash position. If we underestimate demand for our product and, consequently, our component and materials requirements, we may have inadequate inventory, which could interrupt our manufacturing, delay delivery of our product to our customers and result in the loss of customer sales. Any of these occurrences would negatively impact our business and operating results.

We Depend on Sole Source or Limited Source Suppliers. We rely on third parties to manufacture substantially all of the components used in our products, including optics, laser diodes and crystals. We have some long term or volume purchase agreements with our suppliers and currently purchase components on a purchase order basis. Some of our suppliers and manufacturers are sole or limited sources. In addition, some of these suppliers are relatively small private companies that may discontinue their operations at any time. There are risks associated with the use of independent manufacturers, including the following:

- § Shortages or limitations on the ability to obtain supplies of components in the quantities that we require;
- § Delays in delivery or failure of suppliers to deliver critical components on the dates we require;
- § Failure of suppliers to manufacture components to our specifications, and potentially reduced quality; and
- § Inability to obtain components at acceptable prices.

Our business and operating results may suffer from the lack of alternative sources of supply for critical sole and limited source components. The process of qualifying suppliers is complex, requires extensive testing with our products, and may be lengthy, particularly as new products are introduced. New suppliers would have to be educated in our production processes. In addition, the use of alternate components may require design alterations to our products and additional product testing under FDA and relevant foreign regulatory agency guidelines, which may delay sales and increase product costs. Any failures by our vendors to adequately supply limited and sole source components may impair our ability to offer our existing products, delay the submission of new products for regulatory approval and market introduction, materially harm our business and financial condition and cause our stock price to decline. Establishing our own capabilities to manufacture these components would be expensive and could significantly decrease our profit margins. We do not currently intend to manufacture any of these components. Our business, results of operations and financial condition would be adversely affected if we are unable to continue to obtain components in the quantity and quality desired and at the prices we have budgeted.

Our Operating Results May Fluctuate from Quarter to Quarter and Year to Year. Our sales and operating results may vary significantly from quarter to quarter and from year to year in the future. Our operating results are affected by a number of factors, many of which are beyond our control. Factors contributing to these fluctuations include the following:

- General economic uncertainties and political concerns;
- The timing of the introduction and market acceptance of new products, product enhancements and new applications;
- Changes in demand for our existing line of dermatology and ophthalmic products;
- The cost and availability of components and subassemblies, including the ability of our sole or limited source suppliers to deliver components at the times and prices that we have planned;
- Our ability to maintain sales volumes at a level sufficient to cover fixed manufacturing and operating costs;
- Fluctuations in our product mix between dermatology and ophthalmic products and foreign and domestic sales;
- The effect of regulatory approvals and changes in domestic and foreign regulatory requirements;
- Introduction of new products, product enhancements and new applications by our competitors, entry of new competitors into our markets, pricing pressures and other competitive factors;
- Our long and highly variable sales cycle;
- Changes in the prices at which we can sell our products;
- Changes in customers' or potential customers' budgets as a result of, among other things, reimbursement policies of government programs and private insurers for treatments that use our products; and
- Increased product development costs.

In addition to these factors, our quarterly results have been, and are expected to continue to be, affected by seasonal factors.

Our expense levels are based, in part, on expected future sales. If sales levels in a particular quarter do not meet expectations, we may be unable to adjust operating expenses quickly enough to compensate for the shortfall of sales, and our results of operations may be adversely affected. In addition, we have historically made a significant portion of each quarter's product shipments near the end of the quarter. If that pattern continues, any delays in shipment of products could have a material adverse effect on results of operations for such quarter. Due to these and other factors, we believe that quarter to quarter and year to year comparisons of our past operating results may not be meaningful. You should not rely on our results for any quarter or year as an indication of our future performance. Our operating results in future quarters and years may be below expectations, which would likely cause the price of our common stock to fall.

We Depend on Collaborative Relationships to Develop, Introduce and Market New Products, Product Enhancements and New Applications. We depend on both clinical and commercial collaborative relationships. We have entered into collaborative relationships with academic medical centers and physicians in connection with the research and development and clinical testing of our products. Commercially, we currently collaborate with Bausch & Lomb to design and manufacture a solid-state green wavelength (532 nm) laser photocoagulator module, called the Millennium Endolase module. The Millennium Endolase module is designed to be a component of Bausch & Lomb's ophthalmic surgical suite product offering and is not expected to be sold as a stand-alone product. Sales of the Millennium Endolase module are dependent upon the actual order rate from and shipment rate to Bausch & Lomb, which depends on the efforts of our partner and is beyond our control. We cannot assure you that our relationship with Bausch & Lomb will result in further sales of our Millennium Endolase module. We also collaborated with Miravant Medical Technologies, a maker of photodynamic drugs, on a device that emits a laser beam to activate a photodynamic drug developed by Miravant for the treatment of wet AMD. In January 2002, Miravant announced that the top line results of their Phase III clinical trial indicated that PHOTREX, the photodynamic drug developed, did not meet the primary efficacy endpoint in the study population. As we could not be assured that PHOTREX would be timely or successfully pursued through clinical trials by Miravant, we charged to expense in the fourth quarter of 2001, \$0.3 million of inventory related to the OcuLight 664, the laser used by Miravant in the Phase III clinical trials. Miravant has since received an approvable letter from the FDA for PHOTREX with conditions for final marketing approval which includes a request for an additional confirmatory clinical trial. We are the exclusive provider of the OcuLight 664 activation laser used in this application. Successful commercialization of this product will depend, among other things, on the results of the confirmatory clinical trial, acceptance of this product and Miravant's ability to successfully market and sell this therapy. The failure of any current or future clinical or commercial collaboration relationships could have a material adverse effect on our ability to introduce new products or applications and therefore could have a material adverse effect on our business, results of operations and financial condition.

We Face Risks Associated with our Collaborative Relationships. Our collaborators may not pursue further development and commercialization of products resulting from collaborations with us or may not devote sufficient resources to the marketing and sale of such products. Our reliance on others for clinical development, manufacturing and distribution of our products may result in unforeseen problems. Further, our collaborative partners may develop or pursue alternative technologies either on their own or in collaboration with others. If a collaborator elects to terminate its agreement with us, our ability to develop, introduce, market and sell the product may be significantly impaired and we may be forced to discontinue altogether the product resulting from the collaboration. We may not be able to negotiate alternative collaboration agreements on acceptable terms, if at all. The failure of any current or future collaboration efforts could have a material adverse effect on our ability to introduce new products or applications and therefore could have a material adverse effect on our business, results of operations and financial condition.

We Are Subject To Government Regulation Which May Cause Us to Delay or Withdraw the Introduction of New Products or New Applications for Our Products. The medical devices that we market and manufacture are subject to extensive regulation by the FDA and by foreign and state governments. Under the Federal Food, Drug and Cosmetic Act and the related regulations, the FDA regulates the design, development, clinical testing, manufacture, labeling, sale, distribution and promotion of medical devices. Before a new device can be introduced into the market, the product must undergo rigorous testing and an extensive regulatory review process implemented by the FDA under federal law. Unless otherwise exempt, a device manufacturer must obtain market clearance through either the 510(k) premarket notification process or the lengthier premarket approval application (PMA) process. Depending upon the type, complexity and novelty of the device and the nature of the disease or disorder to be treated, the FDA process can take several years, require extensive clinical testing and result in significant expenditures. Even if regulatory approval is obtained, later discovery of previously unknown safety issues may result in restrictions on the product, including withdrawal of the product from the market. Other countries also have extensive regulations regarding clinical trials and testing prior to new product introductions. Our failure to obtain government approvals or any delays in receipt of such approvals would have a material adverse effect on our business, results of operations and financial condition.

The FDA imposes additional regulations on manufacturers of approved medical devices. We are required to comply with the applicable Quality System regulations (QSRs) and our manufacturing facilities are subject to ongoing periodic inspections by the FDA and corresponding state agencies, including unannounced inspections, and must be licensed as part of the product approval process before being utilized for commercial manufacturing. Noncompliance with the applicable requirements can result in, among other things, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, withdrawal of marketing approvals, and criminal prosecution. The FDA also has the authority to request repair, replacement or refund of the cost of any device we manufacture or distribute. Any of these actions by the FDA would materially and adversely affect our ability to continue operating our business and the results of our operations.

In addition, we are also subject to varying product standards, packaging requirements, labeling requirements, tariff regulations, duties and tax requirements. As a result of our sales in Europe, we are required to have all products "CE" marked, an international symbol affixed to all products demonstrating compliance with the European Medical Device Directive and all applicable standards. While currently all of our released products are CE marked, continued certification is based on the successful review of our quality system by our European Registrar during their annual audit. Any loss of certification would have a material adverse effect on our business, results of operations and financial condition.

Our Products Could Be Subject to Recalls Even After Receiving FDA Approval or Clearance. A Recall Would Harm our Reputation and Adversely Affect our Operating Results. The FDA and similar governmental authorities in other countries in which we market and sell our products have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. A government mandated recall, or a voluntary recall by us, could occur as a result of component failures, manufacturing errors or design defects, including defects in labeling. A recall could divert management's attention, cause us to incur significant expenses, harm our reputation with customers and negatively affect our future sales.

If we modify one of our FDA approved or cleared devices, we may need to seek new approvals or clearances which, if not granted, would prevent us from selling our modified products.

Any modifications to an FDA-approved or cleared device that would significantly affect its safety or effectiveness or that would constitute a major change in its intended use would require a new 510(k) clearance or possibly a PMA approval. We may not be able to obtain additional 510(k) clearances or PMA approvals for new products or for modifications to, or additional intended uses or indications for, our existing products in a timely fashion, or at all. Delays in obtaining future clearances would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and future profitability. We have made modifications to our devices and the labeling of our devices in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and stop marketing the modified devices, which could harm our operating results and require us to redesign or relabel our products.

We Rely on Patents and Proprietary Rights to Protect our Intellectual Property and Business. Our success and ability to compete is dependent in part upon our proprietary information. We rely on a combination of patents, trade secrets, copyright and trademark laws, nondisclosure and other contractual agreements and technical measures to protect our intellectual property rights. We file patent applications to protect technology, inventions and improvements that are significant to the development of our business. We have been issued fifteen United States patents and five foreign patents on the technologies related to our products and processes. We have approximately four pending patent applications in the United States and five foreign pending patent applications that have been filed. Our patent applications may not be approved. Any patents granted now or in the future may offer only limited protection against potential infringement and development by our competitors of competing products. Moreover, our competitors, many of which have substantial resources and have made substantial investments in competing technologies, may seek to apply for and obtain patents that will prevent, limit or interfere with our ability to make, use or sell our products either in the United States or in international markets.

In addition to patents, we rely on trade secrets and proprietary know-how which we seek to protect, in part, through proprietary information agreements with employees, consultants and other parties. Our proprietary information agreements with our employees and consultants contain industry standard provisions requiring such individuals to assign to us without additional consideration any inventions conceived or reduced to practice by them while employed or retained by us, subject to customary exceptions. Proprietary information agreements with employees, consultants and others may be breached, and we may not have adequate remedies for any breach. Also, our trade secrets may become known to or independently developed by competitors.

The laser and medical device industry is characterized by frequent litigation regarding patent and other intellectual property rights. Companies in the medical device industry have employed intellectual property litigation to gain a competitive advantage. Numerous patents are held by others, including academic institutions and our competitors. Until recently patent applications were maintained in secrecy in the United States until the patents issued. Patent applications filed in the United States after November 2000 generally will be published eighteen months after the filing date. However, since patent applications continue to be maintained in secrecy for at least some period of time, both within the United States and with regards to international patent applications, we cannot assure you that our technology does not infringe any patents or patent applications held by third parties. We have, from time to time, been notified of, or have otherwise been made aware of, claims that we may be infringing upon patents or other proprietary intellectual property owned by others. If it appears necessary or desirable, we may seek licenses under such patents or proprietary intellectual property. Although patent holders commonly offer such licenses, licenses under such patents or intellectual property may not be offered or the terms of any offered licenses may not be reasonable.

Any claims, with or without merit, and regardless of whether we are successful on the merits, would be time-consuming, result in costly litigation and diversion of technical and management personnel, cause shipment delays or require us to develop noninfringing technology or to enter into royalty or licensing agreements. An adverse determination in a judicial or administrative proceeding and failure to obtain necessary licenses or develop alternate technologies could prevent us from manufacturing and selling our products, which would have a material adverse effect on our business, results of operations and financial condition.

Our Operating Results May be Adversely Affected by Changes in Third Party Coverage and Reimbursement Policies and any Uncertainty Regarding Healthcare Reform Measures. Our ophthalmology products are typically purchased by doctors, clinics, hospitals and other users, which bill various third-party payers, such as governmental programs and private insurance plans, for the health care services provided to their patients. Third-party payers are increasingly scrutinizing and challenging the coverage of new products and the level of reimbursement for covered products. Doctors, clinics, hospitals and other users of our products may not obtain adequate reimbursement for use of our products from third-party payers. While we believe that the laser procedures using our products have generally been reimbursed, payers may deny coverage and reimbursement for our products if they determine that the device was not reasonable and necessary for the purpose used, was investigational or was not cost-effective. In addition, third party payers may not initiate coverage of new procedures using our products for a significant period. In September 2000, the Center for Medicare and Medicaid Services, or CMS, advised that claims for reimbursement for certain age related macular degeneration, or AMD, procedures which use our OcuLight SLx laser system, could be submitted for reimbursement, with coverage and payment to be determined by the local medical carriers at their discretion. To date five carriers representing 17 states have written reimbursement coverage policies on Transpupillary Thermotherapy, or TTT. The states reimbursing for TTT are Alaska, Arizona, California, Colorado, Hawaii, Iowa, Idaho, Mississippi, North Carolina, North Dakota, Nevada, Oregon, Pennsylvania, South Dakota, Tennessee, Washington and Wyoming. Domestic sales of the infrared laser systems may continue to be limited until more local medical carriers reimburse for performing such AMD procedures or until CMS advises that claims for these procedures may be submitted directly to CMS at the national level.

Changes in government legislation or regulation or in private third-party payers' policies toward reimbursement for procedures employing our products may prohibit adequate reimbursement. There have been a number of legislative and regulatory proposals to change the healthcare system, reduce the costs of healthcare and change medical reimbursement policies. Doctors, clinics, hospitals and other users of our products may decline to purchase our products to the extent there is uncertainty regarding reimbursement of medical procedures using our products and any healthcare reform measures. Further proposed legislation, regulation and policy changes affecting third party reimbursement are likely. We are unable to predict what legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future, or what effect such legislation or regulation may have on us. However, denial of coverage and reimbursement of our products would have a material adverse effect on our business, results of operations and financial condition.

If Product Liability Claims are Successfully Asserted Against Us, We may Incur Substantial Liabilities That May Adversely Affect Our Business or Results of Operations. We may be subject to product liability claims from time to time. Our products are highly complex and some are used to treat extremely delicate eye tissue and skin conditions on and near a patient's face. Although we currently maintain and intend to continue the Company's product liability insurance, adequate insurance may not be available on acceptable terms, if at all, and may not provide adequate coverage against potential liabilities. Product liability insurance is expensive. We might not be able to obtain product liability insurance in the future on acceptable terms or in sufficient amounts to protect us, if at all. A successful claim brought against us in excess of our insurance coverage could have a material adverse effect on our business, results of operations and financial condition.

If We Fail to Manage Growth Effectively, Our Business Could Be Disrupted Which Could Harm Our Operating Results. We have experienced, and may continue to experience growth in our business. We have made and expect to continue to make significant investments to enable our future growth through, among other things, new product development and clinical trials for new applications and products. We must also be prepared to expand our work force and to train, motivate and manage additional employees as the need for additional personnel arises. Our personnel, systems, procedures and controls may not be adequate to support our future operations. Any failure to effectively manage future growth could have a material adverse effect on our business, results of operations and financial condition.

If Our Facilities Were To Experience Catastrophic Loss, Our Operations Would Be Seriously Harmed. Our facilities could be subject to catastrophic loss such as fire, flood or earthquake. All of our research and development activities, manufacturing, our corporate headquarters and other critical business operations are located near major earthquake faults in Mountain View, California. Any such loss at any of our facilities could disrupt our operations, delay production, shipments and revenue and result in large expense to repair and replace our facilities.

We May Need Additional Capital, which May Not Be Available, and Our Ability to Grow May be Limited as a Result. We believe that our existing cash balances, available-for-sale securities, credit facilities and cash flow expected to be generated from future operations will be sufficient to meet our capital requirements at least through the next 12 months. However, we may be required, or could elect, to seek additional funding prior to that time. The development and marketing of new products and associated support personnel requires a significant commitment of resources. If cash from available sources is insufficient, we may need additional capital, which may not be available on favorable terms, if at all. If we cannot raise funds on acceptable terms, we may not be able to develop or enhance our products, take advantage of future opportunities, fund potential acquisitions or respond to competitive pressures or unanticipated requirements. Any inability to raise additional capital when we require it would seriously harm our business.

Our Stock Price Has Been and May Continue to be Volatile and an Investment in Our Common Stock Could Suffer a Decline in Value. The trading price of our common stock has been subject to wide fluctuations in response to a variety of factors, some of which are beyond our control, including quarterly variations in our operating results, announcements by us or our competitors of new products or of significant clinical achievements, changes in market valuations of other similar companies in our industry and general market conditions. We receive only limited attention by securities analysts and may experience an imbalance between supply and demand for our common stock resulting from low trading volumes. In addition, the stock market has experienced extreme volatility in the last few years that has often been unrelated to the performance of particular companies. These broad market fluctuations could have a significant impact on the market price of our common stock regardless of our performance.

Changes in Accounting Rules for Stock-Based Compensation Will Adversely Affect Our Operating Results, Our Stock Price and Our Competitiveness in the Employee Marketplace. We have a history of using employee stock options and other stock-based compensation to hire, motivate and retain our workforce. In December 2004, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 123R, "Share-Based Payment," which will require us, commencing for the fiscal year ending 2005, to measure compensation costs for all stock-based compensation (including stock options and our employee stock purchase plan) at fair value and to recognize these costs as expenses in our statement of operations. The recognition of these expenses in our statements of operations will result in lower earnings per share, which could negatively impact our future stock price. In addition, if we reduced or altered our use of stock-based compensation to minimize the recognition of these expenses, our ability to recruit, motivate and retain employees may be impaired, which could put us at a competitive disadvantage in the employee marketplace.

Compliance with Internal Controls Evaluations and Attestation Requirements. Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, we will be required, beginning in fiscal 2006, to perform an evaluation of our internal controls over financial reporting and have our auditor publicly attest to such evaluation. We have prepared an internal plan of action for compliance, which includes a timeline and scheduled activities, although as of the date of this filing we have not yet prepared the evaluation. Compliance with these requirements is expected to be expensive and time-consuming. If we fail to timely complete this evaluation, or if our registered independent public accounting firm cannot timely attest to our evaluation, we could be subject to regulatory scrutiny and a loss of public confidence in our internal controls. In addition, any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our reporting obligations.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

Quantitative Disclosures

We are exposed to market risks inherent in our operations, primarily related to interest rate risk and currency risk. These risks arise from transactions and operations entered into in the normal course of business. We do not use derivatives to alter the interest characteristics of our marketable securities or our debt instruments. We have no holdings of derivative or commodity instruments.

Interest Rate Risk. We are subject to interest rate risks on cash and cash equivalents, available-for-sale marketable securities and any future financing requirements. Interest rate risks related to marketable securities are managed by managing maturities in our marketable securities portfolio. We have no long-term debt as of April 2, 2005.

The fair value of our investment portfolio or related income would not be significantly impacted by changes in interest rates since the marketable securities maturities do not exceed a term of 12 - 14 months and the interest rates are primarily fixed.

Qualitative Disclosures

Interest Rate Risk. Our primary interest rate risk exposures relate to:

- § The risk that available-for-sale securities will fall in value if market interest rates increase.
- § The impact of interest rate movements on our ability to obtain adequate financing to fund future operations.

We have the ability to hold at least a portion of the fixed income investments until maturity and therefore would not expect our operating results or cash flows to be affected to any significant degree by a sudden change in market interest rates on our short- and long-term marketable securities portfolio.

Management evaluates our financial position on an ongoing basis.

Currency Rate Risk.

As all of our sales transactions are denominated in U.S. currency, we do not hedge any balance sheet exposures against future movements in foreign exchange rates. The exposure related to currency rate movements would not have a material impact on future net income or cash flows.

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934 (i) is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission rules and forms and (ii) is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

(b) Changes in Internal Controls

There were no changes in our internal controls over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

The Company is not subject to any material legal proceedings as of the date of this report.

Item 2. Changes in Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Submission of Matters to Vote of Security Holders

None.

Item 5. Other Information

None.

Item 6. Exhibits

[31.1](#) Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

[31.2](#) Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

[32.1](#) Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Trademark Acknowledgments

IRIDEX, the IRIDEX logo, IRIS Medical, OcuLight, SmartKey, EndoProbe and Apex are our registered trademarks. IRIDERM, G-Probe, DioPexy, DioVet, TruFocus, TrueCW, UltraView, DioLite 532, Long Pulse, MicroPulse, ScanLite, ColdTip (Handpiece), VariSpot (Handpiece), TruView and EasyFit product names are our trademarks. All other trademarks or trade names appearing in the Form 10-Q are the property of their respective owners.

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: May 17, 2005

By: /s/ Larry Tannenbaum
Larry Tannenbaum
Chief Financial Officer and Vice President, Administration
Principal Financial Officer,
Chief Accounting Officer and Authorized Signatory)

Exhibit Index

- 31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of Chief Financial pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

EXHIBIT 31.1

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO
SECTION 13(a) OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934 AS
ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF**

I, Theodore A. Boutacoff, certify that:

1. I have reviewed this quarterly report on Form 10-Q of IRIDEX Corporation;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
 - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c) Disclosed in this report any changes in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of the annual report) that has materially affected, or is reasonably likely to materially affect the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 17, 2005

By: /s/ THEODORE A. BOUTACOFF

Name: Theodore A. Boutacoff

Title: President and Chief Executive Officer

(Principal Executive Officer)

EXHIBIT 31.2

**CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO
SECTION 13(a) OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934 AS
ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Larry Tannenbaum certify that:

1. I have reviewed this quarterly report on Form 10-Q of IRIDEX Corporation;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
 - b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c. Disclosed in this report any changes in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of the annual report) that has materially affected, or is reasonably likely to materially affect the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 17, 2005

By: /s/ LARRY TANNENBAUM
Name: Larry Tannenbaum
Title: Chief Financial Officer and Vice President,
Administration
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of IRIDEX Corporation (the "Company") on Form 10-Q for the quarter ending April 2, 2005, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Theodore A. Boutacoff, Chief Executive Officer, and Larry Tannenbaum, Chief Financial Officer, of the Company, each certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 17, 2005

By: /s/ THEODORE A. BOUTACOFF

Name: Theodore A. Boutacoff

Title: President and Chief Executive Officer
(Principal Executive Officer)

Date: May 17, 2005

By: /s/ LARRY TANNENBAUM

Name: Larry Tannenbaum

Title: Chief Financial Officer and Vice President,
Administration
(Principal Financial and Accounting Officer)