UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 30, 2002

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

For the Transition period from to

Commission File Number: 0-27598

IRIDEX CORPORATION

(Exact name of registrant as specified in its charter)

| Delaware | 77-0210467 |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. employer identification No.) |

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

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

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

(1) Yes [X] No [ ]; (2) Yes [X] No [ ]

The number of shares of Common Stock, $.01 par value, issued and outstanding as of May 6, 2002 was 6,862,862.

IRIDEX CORPORATION

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IRIDEX CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS)
(UNAUDITED)

| | MARCH 30, 2002 | DECEMBER 29, 2001 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 5,856 | $ 4,613 |
| Available-for-sale securities | 2,428 | 4,489 |
| Accounts receivable, net | 7,939 | 8,066 |
| Inventories | 12,361 | 12,562 |
| Prepaids and other current assets | 698 | 599 |
| Total current assets | 29,282 | 30,329 |
| Property and equipment, net | 1,418 | 1,535 |
| Deferred income taxes | 1,932 | 1,924 |
| Total assets | $ 32,632 | $ 33,788 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 598 | $ 1,176 |
| Accrued expenses | 2,302 | 2,779 |
| Total liabilities | 2,900 | 3,955 |
| Stockholders' equity: | | |
| Common stock | 70 | 69 |
| Additional paid-in capital | 23,524 | 23,417 |
| Accumulated other comprehensive income | 1 | 3 |
| Treasury stock | (430) | (430) |
| Retained earnings | 6,567 | 6,774 |
| Total stockholders' equity | 29,732 | 29,833 |
| Total liabilities and stockholders' equity | $ 32,632 | $ 33,788 |

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 | |
|---|---|---|
| | MARCH 30, 2002 | MARCH 31, 2001 |
| Sales | $ 6,963 | $ 5,735 |
| Cost of sales | 3,878 | 3,372 |
| Gross profit | 3,085 | 2,363 |
| Operating expenses: | | |
| Research and development | 1,145 | 1,312 |
| Selling, general and administrative | 2,287 | 2,798 |
| Total operating expenses | 3,432 | 4,110 |
| Operating loss from continuing operations | (347) | (1,747) |
| Interest and other income (expense), net | 43 | 140 |
| Loss from continuing operations before benefit from income taxes | (304) | (1,607) |
| Benefit from income taxes | 97 | 683 |
| Loss from continuing operations | (207) | (924) |
| Discontinued operations (Note 4): | | |
| Loss from operations of discontinued Laser Research segment (net of applicable income tax benefit of $0 and $124, respectively) | - | (204) |
| Loss on disposal of Laser Research segment, including provision of $0 and $63, respectively, for operating losses during phase-out period (net of applicable income tax benefit of $0 and $418, respectively) | - | (689) |
| Net loss | $ (207) | $ (1,817) |
| Basic net loss per share: | | |
| Continuing operations | $ (0.03) | $ (0.14) |
| Discontinued operations | - | (0.13) |
| Basic net loss per share: | $ (0.03) | $ (0.27) |
| Shares used in per common shares basic calculations | 6,838 | 6,712 |
| Diluted net loss per share: | | |
| Continuing operations | $ (0.03) | $ (0.14) |
| Discontinued operations | - | (0.13) |
| Diluted net loss per share: | $ (0.03) | $ (0.27) |
| Shares used in per common share diluted calculations | 6,838 | 6,712 |

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 30, 2002 | MARCH 31, 2001 |
| Cash flows from operating activities: | | |
| Net loss | $ (207) | $ (1,817) |
| Adjustments to reconcile net loss to net cash used in continuing operations: | | |
| Discontinued operations | - | 564 |
| Depreciation and amortization | 226 | 204 |
| Provision for inventories | 10 | - |
| Provision for doubtful accounts | (4) | - |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 131 | 1,466 |
| Inventories | 191 | (221) |
| Prepaids and other current assets | (99) | (93) |
| Deferred income taxes | (8) | - |
| Accounts payable. | (578) | (212) |
| Accrued expenses. | (477) | (947) |
| Net cash used in continuing operations. | (815) | (1,056) |
| Cash flows from investing activities: | | |
| Purchases of available-for-sale securities | - | (1,368) |
| Proceeds from maturity of available-for-sale securities. | 2,059 | 111 |
| Acquisition of property and equipment. | (109) | (237) |
| Net cash provided by (used) in investing activities | 1,950 | (1,494) |
| Cash flows from financing activities: | | |
| Issuance of common stock | 108 | 100 |
| Net cash provided by financing activities | 108 | 100 |
| Net increase (decrease) in cash and cash equivalents. | 1,243 | (2,450) |
| Cash and cash equivalents at beginning of period. | 4,613 | 9,998 |
| Cash and cash equivalents at end of period. | $ 5,856 | $ 7,548 |
| SUPPLEMENTAL DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES: | | |
| Change in unrealized gains (losses) on available-for-sale securities | $ (2) | $ 3 |

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 | |
|---|---|---|
| | MARCH 30, 2002 | MARCH 31, 2001 |
| Net loss. . . . . | $ (207) | $ (1,817) |
| Other comprehensive income (loss): | | |
| Change in unrealized gain (loss) on available-for-sale securities. . . . . | (2) | 3 |
| Comprehensive loss. . . . . | $ (209) | $ (1,814) |

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

1. BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements of IRIDEX Corporation have been prepared in accordance with generally accepted accounting principles for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring adjustments, considered necessary for a fair presentation have been included. The condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto, together with management's discussion and analysis of financial condition and results of operations, contained in our Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission on March 29, 2002 (as amended on Form 10K/A on April 10, 2002). The results of operations for the three month period ended March 30, 2002 are not necessarily indicative of the results for the year ending December 28, 2002 or any future interim period.

2. INVENTORIES CONSIST OF THE FOLLOWING (IN THOUSANDS):

| | MARCH 30, 2002 | DECEMBER 29, 2001 |
|---|---|---|
| | (unaudited) | |
| Raw materials and work in progress | $ 7,773 | $ 8,078 |
| Finished goods | 4,588 | 4,484 |
| Total inventories | $ 12,361 | $ 12,562 |

3. COMPUTATIONS OF BASIC AND DILUTED 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. For the periods presented, the Company had losses and, therefore, all common stock equivalents are excluded from the computation of dilutive net loss per share because their effect is antidilutive. Common stock equivalents consist of incremental common shares issuable upon the exercise of stock options.

For the three months ended March 30, 2002 and March 31, 2001, options to purchase 654,678 and 625,406 shares at a weighted average exercise prices of $7.98 and $8.54 were outstanding, but were not included in the computation of diluted net loss per common share because it would have an antidilutive effect. These options could dilute earnings per share in future periods.

4. DISCONTINUED OPERATIONS

In April 2001, management decided to discontinue the Laser Research segment. Revenues of this segment totaled $0 and $25,000 for the three months ended March 30, 2002 and March 31, 2001, respectively. Costs and operating expenses of this segment totaled $0 and $918,000 for the three months ended March 30, 2002 and March 31, 2001, respectively. The total loss on discontinued operations of $893,000 (net of a $542,000 income tax benefit) for the three months ended March 31, 2001 consisted primarily of inventory and sales returns costs. No assets or liabilities of the Laser Research segment remain and no proceeds are expected from the disposition of this segment.

5. BUSINESS SEGMENTS (UNAUDITED)

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 March 30, 2002 and March 31, 2001 is as follows (in thousands):

| | THREE MONTHS ENDED MARCH 30, 2002 | | | THREE MONTHS ENDED MARCH 31, 2001 | | |
|---|---|---|---|---|---|---|
| | Ophthalmology Medical Devices | Dermatology Medical Devices | Total | Ophthalmology Medical Devices | Dermatology Medical Devices | Total |
| Sales | $ 5,078 | $ 1,885 | $6,963 | $ 4,629 | $ 1,106 | $ 5,735 |
| Direct Cost of Goods Sold | 1,672 | 874 | 2,546 | 1,482 | 443 | 1,925 |
| Direct Gross Margin | 3,406 | 1,011 | 4,417 | 3,147 | 663 | 3,810 |
| Total Unallocated Costs | -- | -- | 4,721 | -- | -- | (5,417) |
| Pre-tax Loss | | | (304) | | | (1,607) |

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 on segment assets and liabilities is provided.

ITEM 2. 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, including sales of our OcuLight SLx and Apex 800 laser systems; actual order rate and market acceptance of our products; expectations for future sales growth, generally, and the potential for production cost decreases and higher gross margins; levels of future investment in research and development efforts; favorable Center for Medicare and Medicaid coverage decisions regarding AMD procedures that use our products; results of clinical studies, risks associated with bringing new products to market, general economic conditions, levels of international sales, liquidity and capital resources, and the sufficiency of our existing cash resources. 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. 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 the results of any revision of these forward-looking statements. Actual results could differ materially from those set forth in such forward-looking statements as a result of the factors set forth under "Factors That May Affect Future Operating Results" and other risks detailed in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 29, 2002(as amended on Form 10K/A on April 10, 2002) 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 certain operating data as a percentage of sales for the periods indicated.

| | THREE MONTHS ENDED | |
|---|---|---|
| | MARCH 30, 2002 | MARCH 31, 2001 |
| Sales | 100.0% | 100.0% |
| Cost of sales | 55.7 | 58.8 |
| Gross profit | 44.3 | 41.2 |
| Operating expenses: | | |
| Research and development | 16.4 | 22.9 |
| Sales, general and administrative | 32.9 | 48.8 |
| Total operating expenses | 49.3 | 71.7 |
| Operating loss from continuing operations | (5.0) | (30.5) |
| Other income, net | 0.6 | 2.5 |
| Loss from continuing operations before provision for income taxes | (4.4) | (28.0) |
| Benefit from income taxes | 1.4 | 11.9 |
| Loss from continuing operations | (3.0) | (16.1) |
| Loss from discontinued operations (net of tax) | - | (15.6) |
| Net loss | (3.0)% | (31.7)% |

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 | | | |
|---|---|---|---|---|
| | March 30, 2002 | | March 31, 2001 | |
| | Amount | Percentage of total sales | Amount | Percentage of total sales |
| Domestic | $ 3,998 | 57.4% | $ 3,121 | 54.4% |
| International | 2,965 | 42.6% | 2,614 | 45.6% |
| Total | $ 6,963 | 100.0% | $ 5,735 | 100.0% |
| Ophthalmology: | | | | |
| Domestic | $ 2,817 | 40.4% | $ 2,201 | 38.4% |
| International | 2,261 | 32.5% | 2,428 | 42.3% |
| Total | $ 5,078 | 72.9% | $ 4,629 | 80.7% |
| Dermatology: | | | | |
| Domestic | $ 1,181 | 17.0% | $ 920 | 16.0% |
| International | 704 | 10.1% | 186 | 3.3% |
| Total | $ 1,885 | 27.1% | $ 1,106 | 19.3% |

Combined Ophthalmology and Dermatology Sales

Sales for the three months ended March 30, 2002 increased by 21.4% to $7.0 million from $5.7 million for the three months ended March 31, 2001. The increase was driven primarily by increased unit sales of both our dermatology and ophthalmology products. Domestic sales, which represented 57.4% of total sales, increased by $0.9 million or 28.1% from the comparable prior year three-month period, primarily as a result of unit sales of the new Apex 800 hair removal dermatology laser and increased unit sales of our visible laser systems. International sales, which were 42.6% of total sales, increased by $0.4 million or 13.4% from the comparable prior year three-month period, primarily as a result of unit sales of the Apex 800. We face challenges marketing and selling our products in the current difficult economic environment, both domestically and internationally, and expect to continue to face these challenges for the foreseeable future. See "-Factors That May Affect Future Results - Our Business has been Adversely Impacted by the Current Worldwide Economic Slowdown and Related Uncertainties."

Ophthalmology Sales

Ophthalmology sales increased by 9.7% to $5.1 million for the three months ended March 30, 2002 from $4.6 million for the three months ended March 31, 2001. Domestic ophthalmology sales increased by $0.6 million or 28.0% to $2.8 million for the three months ended March 30, 2002 from $2.2 million for the comparable prior year three-month period. The increase in domestic sales resulted primarily from increased unit sales of our visible laser systems and delivery devices, offset by decreased sales of our infrared laser systems. The increase in visible laser system sales was driven by increased sales focus on these products and also to product improvement resulting from the new Easy Fit adapter. Sales of our infrared laser systems were lower due to uncertainties surrounding reimbursement by the Center for Medicare and Medicaid (CMS) for certain procedures to treat age-related macular degeneration (AMD). International ophthalmology sales decreased by $0.2 million or 6.9% to $2.3 million for the three months ended March 30, 2002 from $2.4 million for the comparable prior year three-month period. The overall decrease in international sales was driven by increased competition related to the strength of the U.S. dollar. General economic conditions also contributed to the overall decrease in international sales.

Dermatology Sales

Dermatology sales increased by $0.8 million or 70.4% to $1.9 million for the three months ended March 30, 2002 from $1.1 million for the three months ended March 31, 2001. Domestic dermatology sales increased by $0.3 million or 28.4% to $1.2 million for the three months ended March 30, 2002 as compared to the comparable prior year three-month period. The increase in domestic sales was driven by unit sales of the new Apex 800, offset in part by decreased unit sales of the DioLite 532 laser system. International dermatology sales increased by $0.5 million to $0.7 million for the three months ended March 30, 2002. The increase in dermatology sales related to unit sales of the new Apex 800 hair removal laser system.

Gross Profit. Our gross profit increased to $3.1 million for the three months ended March 30, 2002 from $2.4 million for the three month period ended March 31, 2001. Gross profit as a percentage of net sales for the three months ended March 30, 2002 increased to 44.3%, compared to 41.2% for the three months ended March 31, 2001, due primarily to the increase in domestic sales. Domestic product sales have higher average sales prices, as they are transacted directly with the user-customer by a direct sales force, as compared to international product sales which are transacted through independent distributors. In addition, fixed manufacturing costs were spread over an overall higher sales volume. Our average selling prices also remained constant during this period. 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.

Research and Development. Our research and development expenses decreased by 12.7% to $1.1 million for the three months ended March 30, 2002 from $1.3 million for the three months ended March 31, 2001. Research and development expenses decreased as a percentage of net sales to 16.4% for the three months ended March 30, 2002 from 22.9% for the comparable prior year three-month period. The decrease in research and development expenses in absolute dollars and as a percentage of net sales during this period was primarily attributable to completion of initial development on the Apex 800 hair removal laser system in 2001 as well as general cost containment measures. We continue to invest in the development of new products with a focus on new instruments and disposable products.

Sales, General and Administrative. Our sales, general and administrative expenses decreased by 18.3% to $2.3 million for the three months ended March 30, 2002 from $2.8 million for the three months ended March 31, 2001. Sales,

general and administrative expenses decreased as a percentage of net sales to 32.9% for the three months ended March 30, 2002 from 48.8% for the comparable prior year three-month period. The decrease in sales, general and administrative expenses, both in absolute dollars and as a percentage of net sales, was primarily due to cost containment measures.

Discontinued Operations. In April 2001, management decided to discontinue the Laser Research segment. Revenues of this segment totaled $0 and $25,000 for the three months ended March 30, 2002 and March 31, 2001, respectively. Costs and operating expenses of this segment totaled $0 and $918,000 for the three months ended March 30, 2002 and March 31, 2001, respectively. The total loss on discontinued operations of $893,000 (net of a $542,000 income tax benefit) for the three months ended March 31, 2001 consisted primarily of inventory and sales returns costs. No assets or liabilities of the Laser Research segment remain and no proceeds are expected from the disposition of this segment.

LIQUIDITY AND CAPITAL RESOURCES

At March 30, 2002, our primary sources of liquidity included cash and cash equivalents and available-for-sale securities in the aggregate amount of $8.3 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 2002. As of March 30, 2002, no borrowings were outstanding under this credit facility. We expect to renew the line of credit in October 2002 assuming that the terms continue to be acceptable.

During the three months ended March 30, 2002, we generated $1.2 million in cash and cash equivalents. During this period, operating activities consumed a net $0.8 million of cash. Uses of cash included a decrease in accounts payable and accrued expenses totaling $1.0 million and an increase in prepaid assets of $0.1 million, offset in part by sources of cash including a net decrease in inventory of $0.2 million, a net decrease in accounts receivable of $0.1 million, and depreciation and amortization of $0.2 million.

We generated $1.9 million in cash in investing activities during the three months ended March 30, 2002, primarily from the net proceeds of $2.0 million of available-for-sale securities offset in part by the acquisition of $0.1 million of property and equipment.

Net cash provided by financing activities during the three months ended March 30, 2002 was $0.1 million which consisted of the issuance of common stock.

We believe that, based on current estimates, our cash and cash equivalents and available-for-sale securities together with cash generated from operations will be sufficient to meet our anticipated cash requirements for the next 12 months.

In December 1998, we instituted a stock repurchase program whereby up to 150,000 shares of our Common Stock may be repurchased in the open market. We plan to utilize all of the reacquired shares for reissuance in connection with employee stock programs. No shares were repurchased during the three months ending March 30, 2002. To date, we have purchased 103,000 shares of our Common Stock under this program.

FACTORS THAT MAY AFFECT FUTURE RESULTS

We Rely on Continued Market Acceptance of Our Existing Products. We currently market visible and infrared light semiconductor-based photocoagulator medical laser systems to the ophthalmic market. We also market a visible and infrared light semiconductor-based photocoagulator medical laser system to the dermatology market. We believe that continued and increased sales, if any, of these medical laser systems is dependent up a number of factors including the following:

- Product performance, procedures and price;

- Recommendations and opinions by ophthalmologists, dermatologists, clinicians, and their associated opinion leaders;

- Performance of these laser systems and treatments which are a beneficial alternative to competing technologies and treatments;

- The willingness of ophthalmologists and dermatologists to convert to semiconductor-based or infrared laser systems from visible argon gas or ion-based laser systems; and

- The level of reimbursement for treatments administered with our products.

Any significant decline in market acceptance of our products 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 dermatological treatments is intense and is expected to increase. This market is also characterized by rapid technological innovation and change and our products could be rendered obsolete as a result of future innovations. Our competitive position depends on a number of factors including product performance, characteristics and functionality, ease of use, scalability, durability and cost. Our principal competitors in ophthalmology are Lumenis, Ltd., Nidek, Inc., Carl Zeiss, Inc., Alcon International and Quantel. All of these companies, all currently offer a competitive semiconductor-based laser system in ophthalmology. Our principal competitors in dermatology are Lumenis Ltd., Laserscope, Candela Corporation and Altus Medical 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 us and long-standing customer relationships. In addition to other companies that manufacture photocoagulators, we compete with pharmaceutical solutions, other technologies and other surgical techniques. Some medical companies, academic and research

institutions or others may develop new technologies or therapies that are more effective in treating conditions targeted by us or are less expensive than our current or future products. Any such developments could have a material adverse effect on our business, financial condition and results of operations.

Our Future Success Depends on Development of New Products and New Applications. Our future success is dependent upon, among other factors, our ability to develop, obtain regulatory approval, manufacture and market new products. Introduction of 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. These variables include price, safety, efficacy, reliability, marketing and sales efforts, the development of new applications for these products, the efficacy of competing products, treatments and techniques and general economic conditions affecting purchasing patterns. Any failure in our ability to successfully develop and introduce new products or enhanced versions of existing products 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.

We Face Risks of Manufacturing. The manufacture of our infrared and visible light photocoagulators and the related delivery devices is a highly complex and precise process. We assemble critical subassemblies and the final product at our facility in Mountain View, California. Although our OcuLight Systems, DioLite 532 and our Apex 800 have been introduced, we continue to face risks associated with manufacturing these products. Various difficulties may occur despite testing. 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.

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. Some of our suppliers and manufacturers are sole or limited source. 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 unavailability of or delays in obtaining adequate supplies of components, including optics, laser diodes, and crystals and potentially reduced control of quality, production costs and timing of delivery. We may experience difficulty identifying alternative sources of supply for certain components used in our products. For example, we experienced delays in shipping our green laser systems (such as the DioLite 532 for dermatology and the OcuLight GL and GLx for ophthalmology) during the first fiscal quarter of 2001 due to a supply shortage of a key component. We qualified additional sources for this component during the first fiscal quarter of 2001; however, the process of qualifying suppliers is ongoing and may be lengthy, particularly as new products are introduced. In addition, the use of alternate components may require design alterations which may delay installation and increase product costs. We have some long term or volume purchase agreements with our suppliers and currently purchase components on a purchase order basis. These components may not be available in the quantities required, on reasonable terms, or at all. Financial or other difficulties faced by our suppliers or significant changes in demand for these components or materials could limit their availability. Any failures by such third parties to adequately perform may impair our ability to offer our existing products, delay the submission of products for regulatory approval, impair our ability to deliver products on a timely basis or otherwise impair our competitive position. Establishing our own capabilities to manufacture these components would be expensive and could significantly decrease our profit margins. Our business and

results of operations 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.

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. In 2001 and 2000, our international sales were $11.3 million and $11.7 million, or 41.3% and 35.6%, respectively, of total sales. For the three months ended March 30, 2002 and March 31, 2001, our international sales were $3.0 million and $2.6 million, representing 42.6% and 45.6%, respectively, 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 have 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. For example, the current high U.S. dollar relative value to the European currency (the Euro) is making our products less competitive in Europe when compared to European competitors and could negatively impact future sales levels from the region. 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 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;

- potentially adverse tax consequences; and

- multiple protectionist, adverse and changing foreign governmental laws and regulations.

The 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 Depend on Third Party Coverage and Reimbursement Policies. Our 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. For example, during July 2000, the Center for Medicare and Medicaid Services (CMS) advised that claims for reimbursement for certain AMD procedures, which use our OcuLight SLx laser system, would not be reimbursed by CMS. As a result, since July 2000, sales of the OcuLight SLx laser system have dropped significantly. In September 2000, CMS changed its position and advised that claims for reimbursement for two of the AMD procedures can be submitted for reimbursement, with coverage and payment to be determined by the local medical carriers in their discretion. Sales of the OcuLight SLx continue, albeit at a lower level, because the OcuLight SLx can

also be used for other retinal procedures with CMS reimbursement. We believe domestic sales of the OcuLight SLx laser system will continue at these lower levels until more 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. Two carriers, Noridian Mutual Insurance, which is the CMS Part B Carrier for Alaska, Arizona, Colorado, Hawaii, Iowa, Nevada, North Dakota, Oregon, South Dakota, Washington and Wyoming, as well as Cigna, which is the carrier for North Carolina, Tennessee and Idaho, have made coverage decisions approving the use of TTT protocol for the treatment of wet AMD. We believe that more medical carriers will reimburse for these procedures and CMS will allow direct reimbursement for them when they are further validated by clinical studies. We are sponsoring a randomized clinical trial to further validate Transpupillary Thermal Therapy, the most significant of the subject AMD procedures.

Changes in government legislation or regulation or in private third-party payers' policies toward reimbursement for procedures employing our products may prohibit adequate reimbursement. Denial of coverage and reimbursement for our products could have a material adverse effect on our business, results of operations and financial condition. 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.

Our Operating Results 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 both preceding and following the terrorist attacks on September 11, 2001;

- The timing of the introduction and market acceptance of new products, product enhancements and new applications;

- Changes in demand for our existing line of dermatological 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;

- Fluctuations in our product mix between dermatological 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;

- Decreases 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. 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.

Our Business Has Been Adversely Impacted By the Worldwide Economic Slowdown and Related Uncertainties. Weaker economic conditions worldwide, particularly in the U.S., have contributed to the current slowdown in our business in general. This has resulted in reduced demand for some of our products, particularly in our dermatology products, such as the Apex 800, excess manufacturing capacity under current market conditions and higher overhead costs, as a percentage of revenue. In addition, these economic conditions are making it very difficult for us, our customers and our distributors to forecast and plan future business activities. This level of uncertainty strongly challenges our ability to operate profitably or grow our business. If the economic or market conditions continue or further deteriorate, this may have a material adverse impact on our financial position, results of operation and cash flows.

We Depend on Collaborative Relationships to Develop, Introduce and Market New Products, Product Enhancements and New Applications. We have entered into collaborative relationships with academic medical centers and physicians in connection with the research and development and clinical testing of our products. We plan to collaborate with third parties to develop and commercialize existing and new products. In May 1996, we executed an agreement with Miravant Medical Technologies, a maker of photodynamic drugs, to collaborate on a device that emits a laser beam to activate a photodynamic drug developed by Miravant for the treatment of wet AMD. The Phase III clinical trial was fully enrolled in December 1999. In January 2002, Miravant announced that the top line results of the trial indicated that SnET2, the photodynamic drug developed, did not meet the primary efficacy endpoint in the study population. As a result, the future place for SnET2 in the treatment of wet AMD is unclear and we cannot assure you that SnET2 will be timely or successfully pursued through clinical trials by Miravant. In the fourth quarter of 2001, we charged to expense $0.3 million of inventory related to the laser used by Miravant in the Phase III clinical trials. Additionally, our reliance on others for clinical development, manufacturing and distribution of our products may result in unforeseen problems. Further, our collaborative partners may develop or pursue alternative technologies either on their own or in collaboration with others. The failure of any current or future collaboration efforts could have a material adverse effect on our ability to introduce new products or applications and therefore could have a material adverse effect on our business, results of operations and financial condition.

We Rely on Patents and Proprietary Rights. Our success and ability to compete is dependent in part upon our proprietary information. We rely on a combination of patents, trade secrets, copyright and trademark laws, nondisclosure and other contractual agreements and technical measures to protect our intellectual property rights. We file patent applications to protect technology, inventions and improvements that are significant to the development of our business. We have been issued twelve United States patents and one foreign patent on the technologies related to our products and processes. We have approximately eight pending patent applications in the United States and

six foreign pending patent applications that have been filed. Our patent applications may not issue as patents, any patents now or in the future may not offer any degree of protection, or our patents or patent applications may be challenged, invalidated or circumvented in the future. Moreover, our competitors, many of which have substantial resources and have made substantial investments in competing technologies, may seek to apply for and obtain patents that will prevent, limit or interfere with our ability to make, use or sell our products either in the United States or in international markets.

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

The laser and medical device industry is characterized by frequent litigation regarding patent and other intellectual property rights. Companies in the medical device industry have employed intellectual property litigation to gain a competitive advantage. Numerous patents are held by others, including academic institutions and our competitors. Because patent applications are maintained in secrecy in the United States until patents are issued and are maintained in secrecy for a period of time outside the United States, we have not conducted any searches to determine whether our technology infringes any patents or patent applications. We have from time to time been notified of, or have otherwise been made aware of, claims that we may be infringing upon patents or other proprietary intellectual property owned by others. If it appears necessary or desirable, we may seek licenses under such patents or proprietary intellectual property. Although patent holders commonly offer such licenses, licenses under such patents or intellectual property may not be offered or the terms of any offered licenses may not be reasonable. This may adversely impact our operating results.

Any claims, with or without merit, could be time-consuming, result in costly litigation and diversion of technical and management personnel, cause shipment delays or require us to develop noninfringing technology or to enter into royalty or licensing agreements. Although patent and intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. An adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our products, which would have a material adverse effect on our business, results of operations and financial condition. Conversely, litigation may be necessary to enforce patents issued to us, to protect trade secrets or know-how owned by us or to determine the enforceability, scope and validity of the proprietary rights of others. Both the defense and prosecution of intellectual property suits or interference proceedings are costly and time consuming.

We Are Subject To Government Regulation. The medical devices that we market and manufacture are subject to extensive regulation by the FDA and by foreign and state governments. Under the FDA Act and the related regulations, the FDA regulates the design, development, clinical testing, manufacture, labeling, sale, distribution and promotion of medical devices. Before a new device can be introduced into the market, the manufacturer must obtain market clearance through either the 510(k) premarket notification process or the lengthier premarket approval ("PMA") application process. Obtaining these approvals can take a long time and delay the introduction of a product. For example, the introduction of the OcuLight GL in the United States was delayed about three months from our expectations due to the longer than expected time period required to obtain FDA premarket clearance. Noncompliance with

applicable requirements, including Quality System Regulations ("QSRs"), can result in, among other things, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the government to grant premarket clearance or premarket approval for devices, withdrawal of marketing approvals, and criminal prosecution. The FDA also has the authority to request repair, replacement or refund of the cost of any device we manufacture or distribute. Our failure to obtain government approvals or any delays in receipt of such approvals would have a material adverse effect on our business, results of operations and financial condition.

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" registered, an international symbol affixed to all products demonstrating compliance to the European Medical Device Directive and all applicable standards. While currently all of our released products are CE registered, continued registration is based on successful review of the process by our European Registrar during their annual audit. Any loss of registration would have a material adverse effect on our business, results of operations and financial condition.

We Must Manage Growth. We have experienced, and may continue to experience growth in production, the number of employees, the scope of our business, our operating and financial systems and the geographic area of our operations. This growth has resulted in new and increased responsibilities for management personnel and our operating, inventory and financial systems. To effectively manage future growth, if any, we have been required to continue to implement and improve operational, financial and management information systems, procedures and controls. We implemented an enterprise-wide management information system in 1998. We must also expand, train, motivate and manage our work force. Our personnel, systems, procedures and controls may not be adequate to support our existing and future operations. Any failure to implement and improve our operational, financial and management systems or to expand, train, motivate or manage employees could have a material adverse effect on our business, results of operations and financial condition.

We Face Product Liability Risks That May Adversely Affect Our Business or Results of Operations. We may be subject to product liability claims in the future. Our products are highly complex and are used to treat extremely delicate eye tissue and skin conditions on and near a patient's face. Although we maintain product liability insurance with coverage limits of $11.0 million per occurrence and an annual aggregate maximum of $12.0 million, our coverage from our insurance policies may not be adequate. Such insurance is expensive and in the future may not be available on acceptable terms, if at all. A successful claim brought against us in excess of our insurance coverage could have a material adverse effect on our business, results of operations and financial condition.

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. 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 us or our competitors or other factors. If we are unable to offset the anticipated decrease in our average selling prices by increasing our sales volumes, our net revenues will decline. In addition, to maintain our gross margins, we must continue to reduce the manufacturing cost of our products. Further, should average unit prices of our current products decline, we must develop and introduce new products and product enhancements with higher margins. 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.

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. If we underestimate demand for our product and, consequently, our component and material 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.

If Our Facilities Were To Experience Catastrophic Loss, Our Operations Would Be Seriously Harmed. Our facilities could be subject to a 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 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 is Volatile. 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 operating results;

- Changes in financial estimates by securities analysts;

- Announcements by us or our competitors of new products or of significant clinical achievements;

- Changes in market valuations of other similar companies; and

- Any deviations in our net sales or levels of profitability from levels expected by securities analysts.

In addition, the stock market has recently experienced extreme volatility 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.

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 March 30, 2002.

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 fiscal year 2002 and the interest rates are primarily fixed.

QUALITATIVE DISCLOSURES

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

- The 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 the operating results or cash flows to be affected to any significant degree by a sudden change in market interest rates on its short- and long-term marketable securities portfolio.

Management evaluates our financial position on an ongoing basis.

Currency Rate Risk

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.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. SUBMISSION OF MATTERS TO VOTE OF SECURITY HOLDERS

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

None.

(b) Reports on Form 8-K

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

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

IRIDEX Corporation
(Registrant)

Date: May 14, 2002

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