IRIDEX CORP
Form 10-Q/A
August 30, 2002

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q/A

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

For the quarterly period ended June 29, 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 August 7, 2002 was 6,862,862.

EXPLANATORY NOTE

This Quarterly Report on Form 10-Q/A ("Form 10-Q/A") is being filed as Amendment No. 1 to the Registrant's Quarterly Report on Form 10-Q for the three and six month periods ended June 29, 2002. This Form 10-Q/A is filed with the Securities and Exchange Commission (the "Commission") for the sole purpose of revising Management's Discussion and Analysis of Financial Condition and Results of Operation as a result of editing errors.

PART I. FINANCIAL INFORMATION

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, expected reductions in employee-related costs due to the recent workforce reduction 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 and risks associated with bringing new products to market, general economic conditions and levels of international sales. 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 as a result of the factors set forth under "Factors That May Affect Future Operating Results" and other risks detailed in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 29, 2002 and detailed from time to time in the reports that we file 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		SIX MONTHS ENDED	
	JUNE 29, 2002	JUNE 30, 2001	JUNE 29, 2002	JUNE 30, 2001
	(UNADITED)		(UNAUDTIED)	
Sales	100.0%	100.0%	100.0%	100.0%
Cost of sales	58.0	47.8	56.9	52.7
Gross profit	42.0	52.2	43.1	47.3
Operating expenses:				
Research and development	17.8	16.6	17.1	19.4
Sales, general and administrative	33.7	37.0	33.3	42.3

Total operating expenses.	51.5	53.6	50.4	61.7
Operating loss from continuing operations	(9.5)	(1.4)	(7.3)	(14.4)
Other income, net	0.7	1.7	0.7	2.0
Income (loss) from continuing operations before benefit from (provision for) income taxes	(8.8)	0.3	(6.6)	(12.4)
Benefit from (provision for) income taxes	2.8	(0.1)	2.1	5.3
Income (loss) from continuing operations.	(6.0)	0.2	(4.5)	(7.1)
Income (loss) from discontinued operations (net of applicable income tax benefit)	0.0	0.0	0.0	(7.0)
Net income (loss)	(6.0)%	0.2%	(4.5)%	(14.1)%

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

	Three Months Ended				Six Months Ended			
	June 29, 2002		June 30, 2001		June 29, 2002		June 30,	
	(Unaudited)				(Unaudited)			
	Amount	Percentage of total sales	Amount	Percentage of total sales	Amount	Percentage of total sales	Amount	Per of s
Domestic	$ 4,744	63.8%	$ 4,038	57.0%	$ 8,743	60.7%	$ 7,160	
International	2,689	36.2%	3,050	43.0%	5,653	39.3%	5,663	
Total	$ 7,433	100.0%	$ 7,088	100.0%	$14,396	100.0%	$12,823	
Ophthalmology:								
Domestic	$ 3,220	43.3%	$ 2,813	39.7%	$ 6,037	41.9%	$ 5,015	
International	2,459	33.1%	2,631	37.1%	4,719	32.8%	5,059	
Total	$ 5,679	76.4%	$ 5,444	76.8%	$10,756	74.7%	$10,074	
Aesthetics:								
Domestic	$ 1,524	20.5%	$ 1,225	17.3%	$ 2,706	18.8%	$ 2,145	
International	230	3.1%	419	5.9%	934	6.5%	604	

Total	$ 1,754	23.6%	$ 1,644	23.2%	$ 3,640	25.3%	$ 2,749	

Combined Ophthalmology and Aesthetics Sales

Sales for the three months ended June 29, 2002 increased 4.9% to $7.4 million for the three months ended June 29, 2002 from $7.1 million for the three months ended June 30, 2001. Sales for the six months ended June 29, 2002 increased 12.3% to $14.4 million from $12.8 million for the six months ended June 30, 2001. For both the three and six month periods the overall increase was driven primarily by increased unit sales of our ophthalmology products and sales of the Apex hair removal laser system for aesthetics offset by a net decrease in average selling prices.

Domestic sales increased 17.5% to $4.7 million from $4.0 million for the comparable prior year three-month period. For the six months ended June 29, 2002 domestic sales increased 22.1% to $8.7 million from $7.2 million. For both the three and six months periods, the increase was due mainly to increased unit sales of our ophthalmology delivery devices and laser systems as well as unit sales of the Apex hair removal laser system for aesthetics offset by decreased average selling prices for domestic products.

International sales decreased 11.8% to $2.7 million for the three months endced June 29, 2002 from $3.0 million for the comparable prior three-month period primarily as a result of decreased unit sales of our ophthalmology visible laser systems and net decreases in average selling prices offset, in part, by increased sales of ophthalmology delivery devices and sales of the Apex hair removal laser system. For the six months ended June 29, 2002 international sales remained constant at $5.7 million.

We continue to face challenges marketing and selling our products in the current difficult economic environment, both domestically and internationally, and expect 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 to $5.7 million for the three months ended June 29, 2002 from $5.4 million for the three months ended June 30, 2001. For the six months ended June 29, 2002 ophthalmology sales increased to $10.8 million from $10.1 million for the comparable prior year six-month period. Domestic ophthalmology sales increased to $3.2 million for the three months ended June 29, 2002 from $2.8 million for the comparable prior year three-month period. For the six months ended June 29, 2002 domestic ophthalmology sales increased to $6.0 million from $5.0 million for the comparable prior year six-month period. For both the three and six month periods domestic ophthalmology sales increased mainly as a result of increased sales of delivery devices and laser systems. International ophthalmology sales decreased to $2.5 million for the three months ended June 29, 2002 from $2.6 million for the comparable prior year three-month period. For the six months ended June 29, 2002 international ophthalmology sales decreased to $4.7 million from $5.1 million for the comparable prior year six-month period. For both the three and six month periods the decrease in international ophthalmology sales was due to decreased sales of visible laser systems offset, in part, by increases in sales of delivery devices.

Aesthetics Sales

Aesthetics sales increased to $1.8 million for the three months ended June 29, 2002 from $1.6 million for the three months ended June 30, 2001. The second quarter of 2001 included approximately $0.4 million of DioLite laser system shipments delayed from the first quarter of 2001 as a result of a key component delay. See "-Factors that May Affect Future Results - We Depend on Sole Source or Limited Source Suppliers." For the six months ended June 29, 2002 aesthetics sales increased to $3.6 million from $2.7 million for the comparable prior year six-month period. Domestic aesthetics sales increased to $1.5 million for the three months ended June 29, 2002 from $1.2 million for the comparable prior year three-month period. For the six months ended June 29, 2002 domestic aesthetics sales increased to $2.7 million from $2.1 million. For both the three and six month periods, the increase in domestic aesthetics sales was driven by sales of the Apex hair removal laser system which commenced shipment in July 2001. International aesthetics sales decreased by $0.2 million to $0.2 million for the three months ended June 29, 2002 from $0.4 million for the comparable prior year three-month period due to the impact of the DioLite system shipments delayed from the first quarter of 2001 which more than offset international sales of the Apex hair removal laser system in the second quarter of 2002. For the six months ended June 29, 2002 international aesthetics sales increased to $0.9 million from $0.6 million mainly as a result of sales of the Apex hair removal laser system. Our aesthetics products sales continue to be affected by the current weak economic conditions, particularly in the United States, and because hair removal procedures completed using our Apex 800 laser system are typically elective procedures that are deferred by patients in difficult economic times. See "-Factors That May Affect Future Results - Our Business has been adversely Impacted by the Current Worldwide Economic Slowdown and Related Uncertainties."

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Gross Profit. Our gross profit decreased 15.6% to $3.1 million for the three months ended June 29, 2002 compared to $3.7 million for the three months ended June 30, 2001. Gross profit as a percentage of net sales for the three months ended June 29, 2002 decreased to 42.0%, compared to 52.2% for the three months ended June 30, 2001. For the six months ended June 29, 2002, gross profit as a percentage of net sales decreased to 43.1% as compared to 47.3% for the six months ended June 30, 2001. For both the three and six month periods ended June 29, 2002, the decrease in gross profit was primarily due to increased overhead costs related mainly to reorganization of our manufacturing and service functions and inventory related charges, lower average selling prices, the addition of lower margin sales of the Apex hair removal laser system and to the reduction in workforce. For the three and six months ended June 29, 2002 the reorganization of our manufacturing and service functions and inventory related charges resulted in an overall decrease in gross profit of approximately $0.3 million while lower average selling prices resulted in a decrease of $0.3 million. 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. 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." Additionally, a portion of our manufacturing costs in the second quarter of 2002 related to reorganization of the manufacturing function and to a reduction in force, and are not expected to recur. Overall, however, 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 Fluctuate from Quarter to Quarter and Year to Year."

Research and Development. Our research and development expenses increased by 12.2% to $1.3 million for the three months ended June 29, 2002 from $1.2 million for the three months ended June 30, 2001. Research and development expenses increased as a percentage of net sales to 17.8% for the three months ended June 29, 2002 from 16.6% for the comparable prior year three-month period. The increase in research and development expense in absolute dollars and as a percentage of sales for the three month period ended June 29, 2002 was due primarily to the launch of new development projects and restructuring charges related to a reduction in work force during the second quarter of 2002. Restructuring charges accounted for approximately $60,000 of the overall increase in research and development expense while the launch of new development projects accounted for the remainder of the increase. For the six month periods ended June 29, 2002 and June 30, 2001, research and development expenses remained relatively constant at approximately $2.5 million. The increase in costs in 2002 as a result of new development projects and restructuring charges was offset by costs in 2001 associated with the completion of development work on the Apex 800 hair removal laser system. Research and development expenses as a percentage of net sales decreased during the period to 17.1% for the six months ended June 29, 2002 from 19.4% for the comparable 2001 period mainly as a result of increased sales in the second half of 2002. The reduction in workforce is expected to reduce research and development employee-related costs by $0.6 million annually going forward.

Sales, General and Administrative. Our sales, general and administrative expenses decreased by 4.3% to $2.5 million for the three months ended June 29, 2002 from $2.6 million for the three months ended June 30, 2001. As a percentage of net sales, sales, general and administrative expenses decreased to 33.7% for the three months ended June 29, 2002 from 37.0% for the comparable prior year

three-month period. For the six months ended June 29, 2002, sales, general and administrative expenses decreased by 11.5% to $4.8 million from $5.4 million for the comparable period in 2001. Sales, general and administrative expenses as a percentage of net sales decreased to 33.3% for the six months ended June 29, 2002 from 42.3% for the comparable period in 2001. The decrease in absolute dollars and as a percentage of net sales for both the three and six month periods ended June 29, 2002 was due primarily to a net decrease in various support related expenses offset by reduction in force related costs in the second quarter of 2002. For both the three and six month periods ended June 29, 2002 the reduction in force related costs were approximately $60,000 while the decrease in various support related expenses made up the remainder of the net decrease in selling, general and administrative expenses. As part of the restructuring during the second quarter of 2002, the ophthalmology and aesthetics marketing functions were combined, allowing for a reduction in operating expenses for these functions. The reduction in workforce is expected to reduce selling, general and administrative employee-related costs by $0.5 million annually going forward.

Discontinued Operations. In April 2001, management decided to discontinue the Laser Research segment. There were no revenues, costs or expenses for this segment for either of the three month periods ended June 29, 2002 and June 30, 2001, respectively. The total loss on discontinued operations of $893,000 (net of a $542,000 income tax benefit) was recorded in the first quarter of 2001 and 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.

Reduction in Force. During the quarter ended June 29, 2002, we reduced our workforce by seventeen positions or approximately 12%. For the three months

ended June 29, 2002, we recorded restructuring charges totaling approximately $150,000 that were related primarily to the severance costs associated with the headcount reduction instituted in the second quarter. The majority of severance costs were paid out in the second quarter of 2002. The reduction in workforce is expected to reduce employee-related costs by $1.2 million annually going forward. As of June 29, 2002, we had a total headcount of 110 full-time employees after the reduction in force.

LIQUIDITY AND CAPITAL RESOURCES

At June 29, 2002, our primary sources of liquidity included cash and cash equivalents and available-for-sale securities in the aggregate amount of $10.0 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 June 29, 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 six months ended June 29, 2002, we generated $1.7 million in cash and cash equivalents. During this period, operating activities provided $1.0 million of cash. Sources of cash from operating activities included a decrease in net accounts receivable of $1.1 million, a decrease in net inventories of $0.7 million and depreciation of $0.4 million, partially offset by uses of cash including a net loss of $0.7 million, a decrease in accounts payable of $0.4 million and a decrease in accrued expenses of $0.2 million. We implemented procedures to reduce overall inventory levels and accounts receivable balances and will continue these asset management efforts to help increase our cash position.

Investing activities provided $0.6 million in cash and cash equivalents during the six months ended June 29, 2002, primarily due to net proceeds from maturity of available for sale securities of $0.8 million offset by $0.2 million for the acquisition of property and equipment.

Net cash provided by financing activities during the six months ended June 29, 2002 was $0.1 million which consisted of the issuance of common stock.

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. However, if the current economic downturn remains protracted, we may need to expend our cash reserves to fund our operations. Our liquidity could be negatively affected by a continued 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 six months ended June 29, 2002. To date, we have purchased 103,000 shares of our common stock under this program.

CRITICAL ACCOUNTING POLICIES

The preparation of our condensed consolidated financial statements in conformity with United States Generally Accepted Accounting Principles (GAAP) requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, net sales and expenses, and the related disclosures. We base our estimates on historical experience, our knowledge of economic and market factors and various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. We believe the following critical accounting policies are affected by significant estimates, assumptions and judgments used in the preparation of our consensed consolidated financial statements.

Revenue Recognition.

Revenue from product sales is recognized upon receipt of a purchase order and product shipment provided no significant obligations remain and collection of the receivables is deemed probable. Up-front fees received in connection with product sales are deferred and recognized over the associated product shipments.

Sales Return Allowance and Allowance for Doubtful Accounts.

In the process of preparing financial statements we must make estimates and assumptions that affect the reported amount of assets and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reported period. Specifically, we must estimate future product returns related to current period product revenue. We analyze historical returns, current economic trends and changes in customer demand and acceptance of our products when evaluating the adequacy of the sales returns allowance and other allowances. Significant management judgments and estimates must be made and used in connection with establishing the sales returns and other allowances in any accounting period. Material differences may result in the amount and timing of our revenue for any period if management made different judgments or utilized different estimates. Similarly our management must make estimates of the uncollectibility of our

accounts receivable. Management specifically analyzes accounts receivable and analyzes historical bad debts, customer concentrations, customer credit-worthiness, current economic trends and changes in our customer payment terms when evaluating the adequacy of the allowance for doubtful accounts. Our accounts receivable balance was $7.0 million, net of allowance for doubtful accounts of $0.2 million as of June 29, 2002.

Inventories.

Inventories are stated at the lower of cost or market. Cost is determined on a standard cost basis which approximates actual cost on a first-in, first-out (FIFO) method. Lower of cost or market is evaluated by considering obsolescence, excessive levels of inventory, deterioration and other factors.

Income Taxes.

Income taxes are accounted for under Statement of Financial Accounting Standards (SFAS) No. 109, "Accounting for Income Taxes." Under SFAS No. 109, deferred assets and liabilities are recognized for the future consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to

taxable income in the years in which those temporary differences are expected to be recovered or settled. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

Warranty Reserves.

We provide reserves for the estimated costs of product warranties at the time revenue is recognized. We estimate the costs of our warranty obligations based on our historical experience of known product failure rates, use of materials, labor and service delivery costs incurred in correcting product failures. In addition, from time to time, specific warranty accruals may be made if unforeseen technical problems arise. Should our actual experience relative to these factors differ from our estimates, we may be required to record additional warranty reserves. Alternatively, if we provide more reserves than we need, we may reverse a portion of such provisions in future periods.

RECENT ACCOUNTING PRONOUNCEMENTS

On April 30, 2002, the Financial Accounting Standards Board (FASB) issued FASB Statement No. 145 (SFAS 145), Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections. FAS 145 rescinds both FASB Statement No. 4 (SFAS 4), Reporting Gains and Losses from Extinguishment of Debt, and the amendment to FAS 4, FASB Statement No. 64 (SFAS 64), Extinguishments of Debt Made to Satisfy Sinking-Fund Requirements. Through this rescission, FAS 145 eliminates the requirement (in both SFAS 4 and SFAS 64) that gains and losses from the extinguishment of debt be aggregated and, if material, classified as an extraordinary item, net of the related income tax effect. However, an entity is not prohibited from classifying such gains and losses as extraordinary items, so long as it meets the criteria in paragraph 20 of Accounting Principles Board Opinion No. 30, Reporting the Results of Operations Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions. Further, SFAS 145 amends paragraph 14(a) of FASB Statement No. 13, Accounting for Leases, to eliminate an inconsistency between the accounting for sale-leaseback transactions and certain lease modifications that have economic effects that are similar to sale-leaseback transactions. The amendment requires that a lease modification (1) results in recognition of the gain or loss in the financial statements, (2) is subject to FASB Statement No. 66, Accounting for Sales of Real Estate, if the leased asset is real estate (including integral equipment), and (3) is subject (in its entirety) to the sale-leaseback rules of

FASB Statement No. 98, Accounting for Leases: Sale-Leaseback Transactions Involving Real Estate, Sales-Type Leases of Real Estate, Definition of the Lease Term, and Initial Direct Costs of Direct Financing Leases. Generally, FAS 145 is effective for transactions occurring after May 15, 2002. We do not expect that the adoption of SFAS 145 will have a material effect on our financial performance or results of operations.

In June 2002, the FASB issued SFAS No. 146, "Accounting for Exit or Disposal Activities" ("SFAS 146"). SFAS 146 addresses significant issues regarding the recognition, measurement, and reporting of costs that are associated with exit and disposal activities, including restructuring activities that are currently accounted for under EITF No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)." The scope of SFAS 146 also includes costs related to terminating a contract that is not a capital lease and termination benefits that employees who are involuntarily terminated receive under the terms of a one-time benefit arrangement that is not an ongoing benefit arrangement or an individual deferred-compensation contract. SFAS 146

will be effective for exit or disposal activities that are initiated after December 31, 2002 and early application is encouraged. The Company will adopt SFAS 146 during the first quarter of 2003. The provision of EITF No. 94-3 shall continue to apply for an exit activity initiated under an exit plan that met the criteria of EITF No. 94-3 prior to the adoption of SFAS 146. The effect on adoption of SFAS 146 will change on a prospective basis the timing of when the restructuring charges are recorded from a commitment date approach to when the liability is incurred. The Company does not expect that the adoption of SFAS 146 will have a material effect on its financial performance or results of operations.

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 aesthetics 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, procedures and price;
- Recommendations and opinions by ophthalmologists and dermatologists;
- 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 alternative technologies; 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 currently offer a competitive semiconductor-based laser system in ophthalmology. Our principal competitors in aesthetics 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 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 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 of, 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 existence of competing products and general economic conditions affecting purchasing patterns. Any failure in our ability to successfully develop and introduce new products or enhanced versions of existing products 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.

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 aesthetics 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 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, DioLite 532 and Apex 800 systems 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 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 suppliers, 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 aesthetics 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, results of operations and financial condition would be adversely affected if we were 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. For the six months ended June 29, 2002 and June 30, 2001, our international sales were $5.7 million for both periods, representing 39% and 44%, 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.

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 Depend on Third Party Coverage and Reimbursement Policies. 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. 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 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 at their discretion. Sales of the OcuLight SLx continue, albeit at a lower level, because the OcuLight SLx can also be used for other ophthalmic procedures with CMS reimbursement. We believe domestic sales of the OcuLight SLx laser system will continue at these lower levels until more local Medicare 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 the TTT protocol for the treatment of wet AMD. We believe that more medical carriers will reimburse for these procedures when they are further validated by clinical studies. We are sponsoring a randomized clinical trial which may further validate Transpupillary Thermotherapy, 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.

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 thirteen 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 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 some 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 Selling Price of our Products, Our Operating Results May Suffer. The average selling 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 selling 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 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.

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, although we are currently in a global economic downturn, 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 or respond to competitive pressures or unanticipated requirements. Any inability to raise additional capital when we require it would seriously harm our business.

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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.

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SIGNATURE

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

IRIDEX Corporation
(Registrant)

Date: August 30, 2002

By: /s/ Robert Kamenski

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

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