

VISX INC
Form 10-Q
November 12, 2003

Table of Contents

**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 September 30, 2003

or

**() 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 1-10694

VISX, INCORPORATED

(Exact name of registrant as specified in its charter)

Delaware

*(State or other Jurisdiction of
Incorporation or Organization)*

06-1161793

*(IRS Employer
Identification No.)*

3400 Central Expressway, Santa Clara, California

(Address of principal executive offices)

95051-0703

(Zip Code)

(Registrant's telephone number, including area code): (408) 733-2020

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

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

Total number of shares of common stock outstanding as of October 31, 2003: 48,330,443

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Interim Financial Statements

CONDENSED CONSOLIDATED BALANCE SHEETS

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

NOTES TO CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Overview

Results of Operations

Liquidity and Capital Resources

Critical Accounting Policies

Risk Factors

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Item 4. Controls and Procedures

Part II. OTHER INFORMATION

Item 1. Legal Proceedings

Item 5. Other Information

Item 6. Exhibits and Reports on Form 8-K

SIGNATURES

Exhibit Index

EXHIBIT 31.1

EXHIBIT 31.2

EXHIBIT 32.1

Table of Contents**VISX, INCORPORATED
TABLE OF CONTENTS**

| | Page |
|--|-------------|
| PART I. FINANCIAL INFORMATION | |
| Item 1. Condensed Consolidated Interim Financial Statements | |
| Condensed Consolidated Balance Sheets as of September 30, 2003 and December 31, 2002 | 3 |
| Condensed Consolidated Statements of Operations for the Three Months Ended September 30, 2003 and 2002 and for the Nine Months Ended September 30, 2003 and 2002 | 4 |
| Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2003 and 2002 | 5 |
| Notes to Condensed Consolidated Interim Financial Statements | 6 |
| Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations | |
| Overview | 10 |
| Results of Operations | 11 |
| Liquidity and Capital Resources | 14 |
| Critical Accounting Policies | 15 |
| Risk Factors | 17 |
| Item 3. Quantitative and Qualitative Disclosures about Market Risk | 22 |
| Item 4. Controls and Procedures | 22 |
| PART II OTHER INFORMATION | |
| Item 1. Legal Proceedings | 23 |
| Item 5. Other Information | 23 |
| Item 6. Exhibits and Reports on Form 8-K | 23 |
| SIGNATURES | 24 |

Table of Contents**PART I. FINANCIAL INFORMATION****Item 1. Condensed Consolidated Interim Financial Statements****VISX, INCORPORATED AND SUBSIDIARIES****CONDENSED CONSOLIDATED BALANCE SHEETS**
(In thousands, except share and per share amounts)

| | September 30, 2003 | December 31, 2002 |
|--|-----------------------|----------------------|
| | (unaudited) | |
| ASSETS | | |
| Current Assets: | | |
| Cash and cash equivalents | \$ 26,090 | \$ 37,687 |
| Short-term investments | 42,908 | 85,268 |
| Accounts receivable, net of allowance for doubtful accounts of \$4,589 and \$2,563, respectively | 24,721 | 24,559 |
| Inventories | 13,109 | 12,751 |
| Deferred tax assets and prepaid expenses | 17,901 | 23,488 |
| | <hr/> | <hr/> |
| Total current assets | 124,729 | 183,753 |
| Property and Equipment, net | 7,833 | 6,498 |
| Long-Term Deferred Tax and Other Assets | 13,413 | 10,341 |
| | <hr/> | <hr/> |
| | \$ 145,975 | \$ 200,592 |
| | <hr/> | <hr/> |
| LIABILITIES AND STOCKHOLDERS EQUITY | | |
| Current Liabilities: | | |
| Accounts payable | \$ 4,004 | \$ 4,341 |
| Accrued liabilities | 33,924 | 41,061 |
| | <hr/> | <hr/> |
| Total current liabilities | 37,928 | 45,402 |
| | <hr/> | <hr/> |
| Long term liabilities | \$ 219 | |
| | <hr/> | <hr/> |
| Stockholders Equity: | | |
| Common stock: \$.01 par value, 180,000,000 shares authorized; 64,990,089 shares issued | 650 | 650 |
| Additional paid-in capital | 200,606 | 202,700 |
| Treasury stock, at cost 16,857,034 and 13,652,256 shares, respectively | (267,119) | (208,748) |
| Accumulated other comprehensive income | 585 | 1,921 |
| Retained earnings | 173,106 | 158,667 |
| | <hr/> | <hr/> |
| Total stockholders equity | 107,828 | 155,190 |
| | <hr/> | <hr/> |
| | \$ 145,975 | \$ 200,592 |
| | <hr/> | <hr/> |

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

Table of Contents**VISX, INCORPORATED AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**
(In thousands, except per share amounts)

| | Three months ended September 30, | | Nine months ended September 30, | |
|---|-------------------------------------|-----------------|------------------------------------|------------------|
| | 2003 | 2002 | 2003 | 2002 |
| (unaudited) | | | | |
| Revenues: | | | | |
| System revenues | \$ 11,136 | \$ 10,216 | \$ 28,743 | \$ 32,935 |
| Service and parts revenues | 4,638 | 4,735 | 13,709 | 14,669 |
| License and other revenues | 23,494 | 15,609 | 63,235 | 56,180 |
| Total revenues | 39,268 | 30,560 | 105,687 | 103,784 |
| Costs and Expenses: | | | | |
| Cost of system revenues | 11,752 | 6,927 | 27,316 | 22,114 |
| Cost of service and parts revenues | 3,574 | 3,805 | 10,685 | 10,749 |
| Cost of license and other revenues | 1,009 | 807 | 2,548 | 2,600 |
| Selling, general, and administrative | 10,538 | 8,831 | 30,846 | 31,675 |
| Research, development and regulatory | 4,814 | 4,601 | 13,649 | 13,625 |
| Total costs and expenses | 31,687 | 24,971 | 85,044 | 80,763 |
| Income From Operations | 7,581 | 5,589 | 20,643 | 23,021 |
| Interest and other income | 369 | 1,505 | 3,130 | 4,597 |
| Income Before Provision For Income Taxes | 7,950 | 7,094 | 23,773 | 27,618 |
| Provision for income taxes | (3,085) | (2,625) | (9,334) | (10,730) |
| Net Income | \$ 4,865 | \$ 4,469 | \$ 14,439 | \$ 16,888 |
| Earnings Per Share | | | | |
| Basic | \$ 0.10 | \$ 0.09 | \$ 0.29 | \$ 0.31 |
| Diluted | \$ 0.10 | \$ 0.08 | \$ 0.28 | \$ 0.31 |
| Shares Used For Earnings Per Share | | | | |
| Basic | 48,065 | 52,483 | 49,816 | 53,620 |
| Diluted | 50,132 | 52,904 | 50,995 | 54,429 |

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

Table of Contents**VISX, INCORPORATED AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**
(In thousands)

| | Nine months ended September 30, | |
|---|--|------------------|
| | 2003 | 2002 |
| | (unaudited) | |
| Cash flows from operating activities: | | |
| Net income | \$ 14,439 | \$ 16,888 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | |
| Depreciation and amortization | 6,518 | 2,851 |
| Provision for doubtful accounts receivable | 2,044 | 1,142 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (2,206) | 6,757 |
| Inventories | (6,053) | (2,806) |
| Deferred tax assets and prepaid expenses | 5,587 | 9,372 |
| Long-term deferred tax and other assets | 1,328 | (710) |
| Accounts payable | (337) | 2,228 |
| Accrued liabilities | (6,918) | (3,789) |
| Net cash provided by operating activities | <u>14,402</u> | <u>31,933</u> |
| Cash flows from investing activities: | | |
| Capital expenditures | (658) | (2,099) |
| Cash paid for acquisition of patents and technology assets | (5,900) | |
| Purchase of short-term investments | (45,853) | (64,580) |
| Sales and maturities of short-term investments | 86,800 | 78,799 |
| Net cash provided by investing activities | <u>34,389</u> | <u>12,120</u> |
| Cash flows from financing activities: | | |
| Exercise of stock options | 2,535 | 4,352 |
| Repurchase of common stock | (63,000) | (39,113) |
| Net cash used in financing activities | <u>(60,465)</u> | <u>(34,761)</u> |
| Effect of exchange rate changes on cash and cash equivalents | <u>77</u> | <u>(1)</u> |
| Net increase (decrease) in cash and cash equivalents | (11,597) | 9,291 |
| Cash and cash equivalents, beginning of period | <u>37,687</u> | <u>15,349</u> |
| Cash and cash equivalents, end of period | <u>\$ 26,090</u> | <u>\$ 24,640</u> |
| Non-Cash Investing Activities: | | |
| Inventory transferred to property and equipment under operating leases | <u>\$ 5,695</u> | <u>\$ 2,568</u> |

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

Table of Contents

VISX, INCORPORATED AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS
September 30, 2003
(Unaudited)

1. Basis of Presentation:

We prepared our Condensed Consolidated Interim Financial Statements in conformity with Securities and Exchange Commission rules and regulations. Accordingly, we condensed or omitted certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles. Please read our 2002 Annual Report on Form 10-K to gain a more complete understanding of these interim financial statements.

These interim financial statements include all adjustments (consisting primarily only of normal recurring adjustments) necessary to present fairly our results for the interim period. Our interim financial statements have not been audited.

Reclassifications. Certain reclassifications were made to prior year financial data to conform with current year presentation.

2. Earnings Per Share:

Basic earnings per share (EPS) equals net income divided by the weighted average number of common shares outstanding. Diluted EPS equals net income divided by the weighted average number of common shares outstanding plus dilutive potential common shares calculated in accordance with the treasury stock method. All amounts in the following table are in thousands, except per share data.

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|-------------------------------------|----------|------------------------------------|-----------|
| | 2003 | 2002 | 2003 | 2002 |
| NET INCOME | \$ 4,865 | \$ 4,469 | \$ 14,439 | \$ 16,888 |
| BASIC EARNINGS PER SHARE | | | | |
| Income available to common stockholders | \$ 4,865 | \$ 4,469 | \$ 14,439 | \$ 16,888 |
| Weighted average common shares outstanding | 48,065 | 52,483 | 49,816 | 53,620 |
| Basic Earnings Per Share | \$ 0.10 | \$ 0.09 | \$ 0.29 | \$ 0.31 |
| DILUTED EARNINGS PER SHARE | | | | |
| Income available to common stockholders | \$ 4,865 | \$ 4,469 | \$ 14,439 | \$ 16,888 |
| Weighted average common shares outstanding | 48,065 | 52,483 | 49,816 | 53,620 |
| Dilutive potential common shares from stock options | 2,067 | 421 | 1,179 | 809 |
| Weighted average common shares and dilutive potential common shares | 50,132 | 52,904 | 50,995 | 54,429 |
| Diluted Earnings Per Share | \$ 0.10 | \$ 0.08 | \$ 0.28 | \$ 0.31 |

Options to purchase 1,996,000 shares and 6,640,000 shares during the three months ended September 30, 2003 and 2002, respectively, were excluded from the computation of diluted EPS because the weighted average exercise prices for these options of \$34.97 and \$21.67, respectively, were greater than the average market price of VISX's common stock during these periods.

Table of Contents

Options to purchase 4,795,000 shares and 6,349,000 shares during the nine months ended September 30, 2003 and 2002, respectively, were excluded from the computation of diluted EPS because the weighted average exercise prices for these options of \$24.46 and \$22.95, respectively, were greater than the average market price of VISX's common stock during these periods.

3. Stock-Based Employee Compensation

We account for stock-based employee compensation arrangements using the intrinsic value method in accordance with the provisions of Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB 25) and Financial Accounting Standards Board (FASB) Interpretation No. 44 (FIN 44), Accounting for Certain Transactions Involving Stock Compensation an Interpretation of APB No. 25 , and comply with the disclosure provisions of Statement of Financial Accounting Standards No. 148, Accounting For Stock-Based Compensation Transition and Disclosure (SFAS 148). In accordance with APB 25 and FIN 44, we record no stock-based employee compensation cost in our net income because (1) all options granted under our stock option plans have an exercise price equal to the market value of the underlying common stock on the date of grant and (2) stock purchased through our Employee Stock Purchase Plan (ESPP) is priced at 85% of the fair market value of the stock on the first day of a two-year offering period or as of the end of each six month purchase segment of a two year offering period, whichever is lower. The following table illustrates the effect on net income and earnings per share if we had applied the fair value recognition provisions of Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation (SFAS 123), to stock-based employee compensation (unaudited, in thousands, except per share data).

| | | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|-------------|-------------------------------------|----------|------------------------------------|-----------|
| | | 2003 | 2002 | 2003 | 2002 |
| Net Income | As Reported | \$ 4,865 | \$ 4,469 | \$ 14,439 | \$ 16,888 |
| Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects | | (1,906) | (2,481) | (6,071) | (7,351) |
| Net Income | Pro Forma | \$ 2,959 | \$ 1,988 | \$ 8,368 | \$ 9,537 |
| Basic Earnings Per Share | As Reported | \$ 0.10 | \$ 0.09 | \$ 0.29 | \$ 0.31 |
| | Pro Forma | 0.06 | 0.04 | 0.17 | 0.18 |
| Diluted Earnings Per Share | As Reported | \$ 0.10 | \$ 0.08 | \$ 0.28 | \$ 0.31 |
| | Pro Forma | 0.06 | 0.04 | 0.17 | 0.18 |

For purposes of computing pro forma net income, we estimate the fair value of each option grant and employee stock purchase plan purchase right on the date of grant using the Black-Scholes option pricing model. The assumptions used to value the option grants and purchase rights are stated as follows:

Table of Contents

| | Three Months Ended | | Nine Months Ended | |
|---|--------------------|--------------------|--------------------|--------------------|
| | September 30, 2003 | September 30, 2002 | September 30, 2003 | September 30, 2002 |
| Expected life of options (in years) | 4.78 | 4.22 | 4.35 | 4.22 |
| Expected life of ESPP rights (in years) | 1.25 | 1.25 | 1.25 | 1.25 |
| Volatility for options | 74% | 79% | 75% | 79% |
| Volatility for ESPP rights | 60% | 65% | 60% | 65% |
| Risk free interest rate for options | 2.32% | 2.46% | 2.46% | 4.16% |
| Risk free interest rate for ESPP rights | 1.63% | 2.04% | 1.61% | 2.04% |
| Dividend yield | 0.0% | 0.0% | 0.0% | 0.0% |

These pro forma amounts may not be representative of the effects for future years as options vest over several years and additional awards are generally made each year.

4. Inventories (in thousands):

| | September 30, 2003 | December 31, 2002 |
|---------------------------------|--------------------|-------------------|
| | (Unaudited) | |
| Raw materials and subassemblies | \$ 7,788 | \$ 8,108 |
| Work in process | 1,560 | 1,563 |
| Finished goods | 3,761 | 3,080 |
| Total | \$13,109 | \$12,751 |

5. Comprehensive Income (unaudited, in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|-------------------------------------|---------|------------------------------------|----------|
| | 2003 | 2002 | 2003 | 2002 |
| NET INCOME | \$4,865 | \$4,469 | \$14,439 | \$16,888 |
| OTHER COMPREHENSIVE INCOME (LOSS) | | | | |
| Change in unrealized holding gains (losses) on available-for-sale securities | (81) | 354 | (1,413) | (620) |
| Change in accumulated foreign currency translation adjustment | 86 | (21) | 77 | (1) |
| COMPREHENSIVE INCOME | \$4,870 | \$4,802 | \$13,103 | \$16,267 |

6. Warranty Obligations

Warranty obligations are included in accrued liabilities. Changes in product warranty obligations for the periods ended September 30, 2003 and 2002 are as follows (unaudited, in thousands):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|-------------------------------------|------|------------------------------------|------|
| | 2003 | 2002 | 2003 | 2002 |

Edgar Filing: VISX INC - Form 10-Q

| | | | | |
|---|----------|---------|----------|----------|
| Balance as of the beginning of the period | \$ 1,663 | \$1,790 | \$ 1,963 | \$ 1,768 |
| Expense accrued for new warranties | 1,700 | 346 | 3,098 | 1,743 |
| Cost of services provided | (1,028) | (421) | (2,726) | (1,796) |
| Balance as of the end of the period | \$ 2,335 | \$1,715 | \$ 2,335 | \$ 1,715 |

Page 8

Table of Contents

7. Patents and Technology Assets

In April 2003, we acquired technology, including patents and other assets associated with our WaveScan WaveFront® System (WaveScan System) from 20/10 Perfect Vision Optische Gerate GmbH. We paid \$5.9 million for this technology, which was previously licensed to us under an exclusive licensing agreement that is superseded by the acquisition. These assets are included in other assets and are being amortized to cost of system revenues over the estimated useful life of five years.

8. Stock Repurchase Program

On April 4, 2001, our Board of Directors authorized a Stock Repurchase Program under which up to 10 million shares of VISX common stock may be repurchased. In accordance with this authorization and applicable securities laws, we have repurchased 7.0 million shares cumulatively on the open market through September 30, 2003, at a total cost of \$90.4 million. Accordingly, 3.0 million shares remain available as of September 30, 2003 for repurchase under the Board of Directors April 2001 authorization. Additionally, on May 28, 2003, the Board of Directors authorized the repurchase of an additional 3.5 million shares of VISX stock at a total cost of \$63 million, all of which were purchased during the quarter ended June 30, 2003.

9. Significant Customer

A significant portion of our revenues is derived from sales to TLC Vision Corporation (TLC), formed in May 2002 through the merger of TLC Laser Eye Centers, Inc. and Laser Vision Centers, Inc., both long-term customers of ours. Sales to TLC and its operating subsidiaries accounted for 17% and 12% of total revenues in the third quarter of 2003 and 2002, respectively, and 16% and 15% of total revenues in the first nine months of 2003 and 2002, respectively.

At September 30, 2003, TLC represented 23% of accounts receivable. At December 31, 2002, TLC represented 22% of accounts receivable.

10. Legal Proceedings

From time to time, we have been involved in a variety of legal proceedings. For a complete description of legal proceedings, see our annual report on Form 10-K for the year ended December 31, 2002 and our quarterly reports on Form 10-Q for the quarters ended March 31, 2003 and June 30, 2003. During the quarter ended September 30, 2003, there were no material developments with respect to such previously existing proceedings and no new material proceedings not previously disclosed.

11. New Accounting Pronouncement

In November 2002, the EITF reached a consensus on Issue No. 00-21, Revenue Arrangements with Multiple Deliverables. EITF Issue No. 00-21 provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The provisions of EITF Issue No. 00-21 apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The adoption of EITF Issue No. 00-21 did not have a material impact on our financial position or results of operations.

Table of Contents

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

This Report contains forward-looking statements, including but not limited to: declining laser upgrade revenues in 2003 as compared to 2002; our belief that a rebound in the United States economy and increases in consumer confidence will provide renewed support for the United States laser vision correction market in the future; our belief that ongoing technical advances (including our CustomVue procedure) have the potential to improve a person's vision beyond that which can be obtained with contact lenses or glasses and will reduce concerns perceived by some consumers; research and development and regulatory expenditures; our belief that gross profit margin on system revenues will remain lower than the comparative 2002 period throughout the remainder of 2003; the sufficiency of our cash flow from operations combined with our existing cash, cash equivalents and short-term investments to meet our needs during the coming twelve months; our belief that our interest and other income for the remainder of 2003 will be significantly lower than the comparative 2002 periods; and our belief that legal actions will not materially affect our business. These forward-looking statements are estimates reflecting the best judgment of our senior management, and they involve a number of risks and uncertainties that could cause actual results to differ materially from those suggested by the forward-looking statements. The risks and uncertainties include the potential reduction in demand for our equipment and upgrades, as well as the potential decline in demand for procedures caused by the weakness in the economy, consumer confidence or stock markets in the United States. In addition, please see the disclosure under the caption "Risk Factors" at the end of Item 2. Moreover, we caution you not to place undue reliance on these forward-looking statements, which speak only as of the date they were made. We do not undertake any obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date of this report or to reflect the occurrence of unanticipated events.

The laser vision correction industry is continually evolving. Economic, market, and technology changes frequently affect VISX and could harm our business in the future. If any of the risks referred to above were to materialize, orders and revenues for the VISX STAR Excimer Laser System (VISX STAR System), WaveScan Wavefront® System (WaveScan System) and/or treatment cards for standard or CustomVue procedures could fluctuate or decline. Accordingly, our past results may not be useful in predicting our future results.

Overview

VISX, Incorporated (VISX), a Delaware corporation organized in 1988, is a worldwide leader in the design and development of proprietary technologies and systems for laser vision correction. We sell products worldwide and generate the majority of our revenues through the sale of treatment cards that are used to perform laser vision correction procedures on the VISX STAR System. We have also licensed our technology to other excimer laser system companies and generally receive royalties from the sale of their systems outside the United States and from procedures that are performed in the United States using their systems.

The Food and Drug Administration (FDA) in the United States and comparable regulatory agencies in other countries have approved the VISX STAR System for use in the treatment of most types of refractive vision disorders, including nearsightedness, farsightedness and astigmatism. The FDA has also approved our WaveScan System, a diagnostic device that measures refractive errors in a person's vision more precisely than previously available technology. The WaveScan System is used in conjunction with our VISX STAR System to perform CustomVue laser vision correction, which enhances laser vision correction and potentially improves vision beyond that possible with contacts and glasses. In May 2003, we received FDA approval of our CustomVue procedure for the treatment of myopia and astigmatism.

Table of Contents**Results of Operations**

| REVENUES (000 s) | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|----------------------------------|----------------------------------|--------------|--------|---------------------------------|--------------|--------|
| | 2003 | 2002 | Change | 2003 | 2002 | Change |
| System revenues | \$ 11,136 | \$ 10,216 | 9% | \$ 28,743 | \$ 32,935 | (13)% |
| <i>Percent of total revenues</i> | <i>28.4%</i> | <i>33.4%</i> | | <i>27.2%</i> | <i>31.8%</i> | |
| Service and parts revenues | 4,638 | 4,735 | (2)% | 13,709 | 14,669 | (7)% |
| <i>Percent of total revenues</i> | <i>11.8%</i> | <i>15.5%</i> | | <i>13.0%</i> | <i>14.1%</i> | |
| License and other revenues | 23,494 | 15,609 | 51% | 63,235 | 56,180 | 13% |
| <i>Percent of total revenues</i> | <i>59.8%</i> | <i>51.1%</i> | | <i>59.8%</i> | <i>54.1%</i> | |
| Total | \$ 39,268 | \$ 30,560 | 28% | \$ 105,687 | \$ 103,784 | 2% |

System revenues

System revenues are comprised of the following: revenues from sales of the VISX STAR System, revenues from the sales of upgrades to the VISX STAR System, and revenues from the sales of the WaveScan System®. Overall, system revenues increased \$0.9 million, to \$11.1 million for the three months ended September 30, 2003 from \$10.2 million for the three months ended September 30, 2002. System revenues decreased \$4.2 million, to \$28.7 million for the nine months ended September 30, 2003 from \$32.9 million for the nine months ended September 30, 2002.

Sales of the VISX STAR System declined \$1.2 million and \$6.4 million in the third quarter and nine months, respectively, from the comparable periods of the prior year. The United States and many of our key international markets began to experience an economic slowdown in the later part of 2000 that has continued into 2003. This has led to industry-wide reductions in procedure volume in the United States as well as in many key international markets during this period. We believe the reduction in procedure volume is the principle cause for the decline in demand for new lasers. We also believe that economic slowdown was responsible for the decline in our average selling price for VISX STAR Systems in the United States as compared to the prior year.

Upgrade revenues declined \$1.7 million and \$7.8 million in the third quarter and first nine months of 2002, respectively, from the comparable periods of the prior year. The decline in upgrade revenues was due to the fact that approximately 90% of our lasers in active use in the United States have already been upgraded to the STAR S3® platform. We anticipate that upgrade revenues throughout 2003 will be significantly lower than in 2002.

WaveScan System sales increased \$3.8 million and \$10.0 million in the third quarter and first nine months of 2002, respectively, over the comparable periods of the prior year due to the CustomVue approval in May 2003 that had been long anticipated by our customers.

Service and parts revenues

Service and parts revenues decreased \$0.1 million, to \$4.6 million for the three months ended September 30, 2003, from \$4.7 million for the three months ended September 30, 2002. Service and parts revenues decreased \$1.0 million, to \$13.7 million for the nine months ended September 30, 2003, from \$14.7 million for the nine months ended September 30, 2002. The declines were due mainly to a new service plan introduced during 2002 that reduced the price charged for service contracts on laser systems with lower than average procedure volume.

Table of Contents*License and other revenues*

License and other revenues increased \$7.9 million, to \$23.5 million for the three months ended September 30, 2003, from \$15.6 million for the three months ended September 30, 2002. License and other revenues increased \$7.0 million, to \$63.2 million for the nine months ended September 30, 2003, from \$56.2 million for the nine months ended September 30, 2002. These increases are attributable primarily to customers in the United States purchasing treatment cards for our new CustomVue procedure, which was introduced in June 2003. Our selling price for the CustomVue procedure is more than double that for our standard procedure. In addition, procedure volume increased slightly in the third quarter of 2003, reversing our normal seasonal decline in procedure volume from the second to the third quarter.

We believe that a rebound in the United States economy and increases in consumer confidence will provide renewed support for the United States laser vision correction market. We also expect that ongoing technical advances (including our CustomVue procedure), which have the potential to improve a person's vision beyond that which can be obtained with contact lenses or glasses, will reduce concerns perceived by some consumers regarding the safety of laser vision correction. Nevertheless, we cannot accurately predict when, or to what extent, these anticipated changes in the economy and technology will impact our license and other revenues.

| COSTS & EXPENSES (000 \$) | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|------------------------------------|----------------------------------|--------------|--------|---------------------------------|--------------|--------|
| | 2003 | 2002 | Change | 2003 | 2002 | Change |
| Cost of system revenues | \$ 11,752 | \$ 6,927 | 70% | \$ 27,316 | \$ 22,114 | 24% |
| <i>Percent of related revenues</i> | <i>105.5%</i> | <i>67.8%</i> | | <i>95.0%</i> | <i>67.1%</i> | |
| Cost of service and parts revenues | 3,574 | 3,805 | (6)% | 10,685 | 10,749 | (1)% |
| <i>Percent of related revenues</i> | <i>77.1%</i> | <i>80.4%</i> | | <i>77.9%</i> | <i>73.3%</i> | |
| Cost of license and other revenues | 1,009 | 807 | 25% | 2,548 | 2,600 | (2)% |
| <i>Percent of related revenues</i> | <i>4.3%</i> | <i>5.2%</i> | | <i>4.0%</i> | <i>4.6%</i> | |
| Selling, gen'l and admin | 10,538 | 8,831 | 19% | 30,846 | 31,675 | (3)% |
| <i>Percent of total revenues</i> | <i>26.8%</i> | <i>28.9%</i> | | <i>29.2%</i> | <i>30.5%</i> | |
| Research, develop. and regulatory | 4,814 | 4,601 | 5% | 13,649 | 13,625 | 0% |
| <i>Percent of total revenues</i> | <i>12.3%</i> | <i>15.1%</i> | | <i>12.9%</i> | <i>13.1%</i> | |

Cost of system revenues

Cost of system revenues increased \$4.8 million, to \$11.8 million for the three months ended September 30, 2003, from \$6.9 million for the three months ended September 30, 2002. Cost of system revenues increased \$5.2 million, to \$27.3 million for the nine months ended September 30, 2003, from \$22.1 million for the nine months ended September 30, 2002. Sales of VISX STAR Systems and system upgrades decreased while shipments of WaveScan Systems increased. The increase in cost of system revenues was due primarily to higher costs related to increased WaveScan System revenue. Cost of system revenues as a percent of WaveScan System revenue in 2003 was higher than the cost of system revenues percentage on VISX STAR Systems and system upgrade revenue in 2002. In addition, our gross profit margin on system revenues declined in 2003 from 2002 because we sold fewer VISX STAR Systems and system upgrades and we earned less revenue on average per unit sold. Furthermore, we recorded a negative gross profit margin in the three months ended September 30, 2003 as additional costs of system revenues were incurred for the support related to the introduction of our CustomVue products. We believe that our gross profit margin on system revenues for the remainder of 2003 will be lower than in the comparable period of 2002. However, we do not anticipate a negative gross profit margin on system revenues during the coming twelve months.

Table of Contents

Cost of service and parts revenues

Cost of service and parts revenues decreased \$0.2 million, to \$3.6 million for the three months ended September 30, 2003, compared to \$3.8 million for the three months ended September 30, 2002. Cost of service and parts revenues was largely unchanged in the nine months ended September 30, 2003, from the corresponding period of the prior year. Cost of service and parts revenues decreased due to a large installed base of stable products in the United States that required fewer repairs. The gross profit margin on service and parts revenues was lower in the nine months ended September 30, 2003 than in the comparable period of 2002 due primarily to the lower price associated with a new service plan introduced during 2002.

Cost of license and other revenues

Cost of license and other revenues increased \$0.2 million, to \$1.0 million for the three months ended September 30, 2003, from \$0.8 million for the three months ended September 30, 2002. Cost of license and other revenues was largely unchanged in the nine months ended September 30, 2003, from the corresponding period of the prior year. This increase was due to the sale of more treatment cards in 2003 when compared to the related period in 2002.

Selling, general, and administrative expenses

Selling, general, and administrative expenses (S,G&A) increased \$1.7 million, to \$10.5 million for the three months ended September 30, 2003, from \$8.8 million for the three months ended September 30, 2002. Selling, general, and administrative expenses decreased \$0.9 million to \$30.8 million for the nine months ended September 30, 2003 from \$31.7 million for the nine months ended September 30, 2002. S,G&A expense in the third quarter of 2003 included \$1.5 million higher charges for bad debt expense over the comparable period of 2002. DVI Inc. (DVI), which provided equipment purchase financing to VISX customers, entered into Chapter 11 bankruptcy proceedings on August 25, 2003. We recorded bad debt expense to increase our reserve for doubtful accounts to cover the entire \$2.3 million of accounts receivables then outstanding from DVI. This was the primary cause for the increase in bad debt expense over the comparable period of 2002. Otherwise, higher marketing and sales expenses incurred to promote our new CustomVue procedure largely offset lower administration expenses. The decline in S,G&A for the first nine months of 2003 from the comparable period of 2002 resulted principally from two offsetting factors. Legal expenses declined by \$4.8 million due to the settlement reached with Nidek in the first quarter of 2003. Legal expenses are net of insurance reimbursements of \$2.3 million and \$5.0 million received in the first nine months of 2003 and 2002, respectively. Marketing and sales expenses increased \$3.7 million in support of the launch of our new CustomVue procedure.

Research, development and regulatory expenses

Research, development and regulatory expenses increased \$0.2 million to \$4.8 million for the three months ended September 30, 2003, from \$4.6 million for the three months ended September 30, 2002. Research, development and regulatory expenses were consistent between the nine months ended September 30, 2003 and 2002. We continued to focus on next generation technologies and developments for laser vision correction. These included laser platforms such as our STAR S4 Excimer Laser System, eye diagnostic units such as our WaveScan System, and new methods for correcting vision disorders including our CustomVue procedure and early research and clinical trials on treatments for presbyopia. We also fund early stage research at Stanford University for future treatments for age-related macular degeneration (AMD) and other advanced technologies. We anticipate that our research, development and regulatory expenses in 2003 will be consistent with our expenditures in 2002.

Table of Contents*Interest and other income*

Our average balance of cash invested in interest bearing securities was lower in 2003 than in 2002 due to cash used to repurchase our stock. Additionally, our average yields on our portfolio of cash and investments was lower in 2003 compared to 2002. Accordingly, interest income declined in 2003 from 2002 during both the three month and nine month periods ended September 30. We anticipate that our interest and other income for the remainder of 2003 will be significantly lower than during the comparative 2002 period due to our reduced cash, cash equivalents and short-term investments as of September 30, 2003 and lower market interest rates.

Liquidity and Capital Resources

Cash, cash equivalents and short-term investments and working capital were as follows:

| | (000 s) | |
|---|-----------------------|----------------------|
| | September 30, 2003 | December 31, 2002 |
| | (Unaudited) | |
| Cash, cash equivalents and short-term investments | \$ 68,998 | \$ 122,955 |
| Working capital | 86,801 | 138,351 |
| Stockholders' equity | 107,828 | 155,190 |

Our cash, cash equivalents, and short-term investments consist principally of money market funds, and government and corporate bonds. All of our short-term investments are classified as available-for-sale under the provisions of Statement of Financial Accounting Standards No. 115, Accounting for Certain Investments in Debt and Equity Securities. The securities are carried at fair market value with the unrealized gains and losses, net of tax, included in accumulated other comprehensive income, which is reflected as a separate component of stockholders' equity. Realized gains and losses are recognized when realized on the consolidated statements of operations.

Cash, cash equivalents, and short-term investments decreased by \$54.0 million in the first nine months of 2003 principally because of stock repurchases of \$63.0 million for the nine months ended September 30, 2003.

Operating activities provided \$14.4 million of cash in the first nine months of 2003, down from \$31.9 million provided in the first nine months of 2002. Net cash provided by operating activities, in the nine months ended September 30, 2003, consisted primarily of net income, net of non-cash related expenses of \$8.6 million. This was partially offset by a decrease in accrued liabilities due primarily to a payment to Nidek as settlement for antitrust and related claims.

Net cash provided by investing activities was \$34.4 million in the first nine months of 2003, compared to net cash provided by investing activities of \$12.1 million in the first nine months of 2002. Net cash provided by investing activities consisted primarily of the proceeds from the sale of short-term investments. This was partially offset in 2003 by a payment of \$5.9 million for acquired patents and technology assets from 20/10 Perfect Vision Optische Gerate GmbH.

Net cash used in financing activities was \$60.5 million in the first nine months of 2003, compared to net cash used in financing activities of \$34.8 million in the first nine months of 2002. Cash of \$63.0 million in 2003 and \$39.1 million in 2002 was used to repurchase approximately 3.5 million shares in open market transactions during the first nine months of each year. This was partially offset by cash received upon the exercise of stock options totaling \$2.5 million during the first nine months of 2003 as compared to \$4.4 million in the comparable period of 2002.

Table of Contents

On April 4, 2001, our Board of Directors authorized a Stock Repurchase Program under which up to 10 million shares of VISX common stock may be repurchased. In accordance with this authorization and applicable securities laws, we have repurchased 7.0 million shares on the open market cumulatively through September 30, 2003, at a total cost of \$90.4 million. Accordingly, 3.0 million shares remain available as of September 30, 2003 for repurchase under the Board of Directors' April 2001 authorization. Additionally, on May 28, 2003, the Board of Directors authorized the repurchase of an additional 3.5 million shares of VISX stock at a total cost of \$63 million, all of which were purchased during the quarter ended June 30, 2003. Before repurchasing shares we consider a number of factors including market conditions, the market price of the stock, and the number of shares needed for employee benefit plans. As a result, we cannot predict the number of shares that we may repurchase in the future.

Purchases of short-term investments represent reinvestment into short-term investments of the proceeds from short-term investments that matured and investment of cash and cash equivalents. As of September 30, 2003, we did not have any borrowings outstanding nor any credit agreements.

Our normal credit terms granted to customers are net 30 to 60 days. In an effort to promote the growth of the laser vision correction industry and the use of VISX STAR Systems and WaveScan Systems, we provide long-term financing to customers for their purchase of our equipment in certain markets. We consider a number of factors including industry practice, competition, and our evaluation of customers' credit worthiness in determining when to offer such financing.

We believe our operations will provide sufficient cash flow to meet our working capital and capital equipment needs during the coming twelve months. In addition, we have \$69 million in cash, cash equivalents, and short-term investments as of September 30, 2003 to provide for unforeseen contingencies and to support strategic objectives including the development or acquisition of new technologies and our Stock Repurchase Program.

In May 2002, we entered into an exclusive worldwide license agreement for a portfolio of patents held by Luis Ruiz, MD, relating to the treatment of presbyopia with multifocal ablations. VISX also signed an agreement with Tracey Technologies, LLC for rights to Tracey's ray tracing technology for use in customized laser vision correction treatments. If clinical and regulatory milestones specified in both agreements are achieved, VISX will be committed to make additional payments of approximately \$2 million in connection with these two agreements. VISX could be obligated for royalties in the future based on any future sales of the associated products.

Critical Accounting Policies

We follow accounting principles generally accepted in the United States (GAAP) in preparing our financial statements. As part of this work, we must make many estimates and judgments about future events. These affect the value of the assets and liabilities, contingent assets and liabilities, and revenues and expenses reported in our financial statements. We believe these estimates and judgments are reasonable and we make them in accordance with our accounting policies based on information available at the time. However, actual results could differ from our estimates and could require us to record adjustments to expenses or revenues material to our financial position and results of operations in future periods. Our critical accounting policies used in making these estimates and judgments are as follows.

Table of Contents

Revenue Recognition

Our revenue is comprised of the following: sale and rental of equipment and upgrades, service revenue, and license fees and related procedure revenue (procedure revenue). We recognize revenue in accordance with SEC Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements (SAB 101). Under this standard, revenue is generally recognized when the following four criteria are met:

- (1) Persuasive evidence of an arrangement exists;
- (2) Delivery has occurred or services have been rendered;
- (3) Our selling price is fixed or determinable; and
- (4) Collectibility is reasonably assured.

All of our sales are documented by contract or purchase orders specifying sales prices and terms.

We sell directly to end customers in the United States. Within the United States and Japan we directly handle installation of our equipment and upgrades and recognize revenue on these products after we have completed installation at a customer's site. We also accrue an estimate of the cost of warranty service to be provided in the future. Outside the United States and Japan our standard terms are FOB VISX, and we sell through independent, third party distributors who are generally responsible for all marketing, sales, installation, training and warranty labor coverage for our products. Accordingly, we recognize system revenue when we ship equipment for customers outside the United States and Japan and accrue an estimate of the cost of parts that we are obligated to provide under warranty. Under sales type lease agreements, system revenues are recognized upon shipment or installation, as appropriate. Under rental or operating lease agreements for systems, rental revenue is recognized over the term of the agreement. For customers who purchase service contracts, we recognize service revenue over the term of the contract. Payments received in advance of services performed are recorded as deferred revenue. For customers without service contracts, we recognize service revenue when we provide service. We record spare parts revenue upon shipment of the parts. We recognize license fees and related procedure revenue from direct customers when we ship treatment cards. We recognize license fees from third party licensees when we receive payment. We classify shipping costs, net of any billings, in cost of revenues.

We assess the credit worthiness of all customers in connection with their purchases. We only recognize revenue when collectibility is reasonably assured. If this is not the case, then we record revenue only as payments are received.

Accounts Receivable

Customers are evaluated for credit worthiness and we recognize revenue when collectibility is reasonably assured. At the end of each accounting period, we estimate the reserve necessary for accounts receivables that will ultimately not be collected from customers. To develop this estimate, we review all receivables and identify those accounts with problems. For these problem accounts, we estimate individual, specific reserves based on our analysis of the payment history, operations and finances of each account. For all other accounts, we review historical bad debt trends, general and industry specific economic trends, customer concentrations, and current payment patterns to estimate the reserve necessary to provide for payment defaults that cannot be specifically identified but can be expected with reasonable probability to occur in the future. We face two particular challenges in estimating these reserves: concentration of credit with certain large customers and the potential for significant change in the overall health of the

Table of Contents

national economies in the markets we serve. Unexpected deterioration in the health of either a large customer or a national economy could lead to a material adverse impact on the collectibility of our accounts receivable and our future operating results.

Inventories

Inventories consist of purchased parts, subassemblies and finished systems and are stated at the lower of cost or market, using the first-in, first-out method. We regularly review our inventory on hand plus on order and compare this to our estimate of demand over the following six months. Based on this analysis, we reduce the carrying value of our inventory for excess and obsolete items. New products and changes in competition, the economy, and technology can lead to variation in demand for our products. If the change in demand is significant, we may need to further reduce the carrying value of our inventory. All inventory write-downs result in a new cost basis and are charged to cost of revenues; accordingly, any inventory write-down would impact our reported cost of revenues.

Legal Contingencies

At the end of each accounting period, we review all outstanding legal matters. If we believe it is probable that we will incur a loss as a result of the resolution of a legal matter and we can reasonably estimate the amount of the loss, we accrue our best estimate of the potential loss. It is very difficult to predict the future results of complex legal matters. New developments in legal matters can cause changes in previous estimates and result in significant changes in loss accruals. Currently we are not aware of any legal actions against us or threatened that we believe could materially adversely affect our business, financial condition or results of operations. However, we could in the future be subject to litigation claims that could cause us to incur significant expenses and put our business, financial position, and results of operations at material risk.

Risk Factors

This report contains forward-looking statements that involve risk and uncertainty. The factors set forth below, which are not the only risks we face, may cause our actual results to vary from those contemplated by certain forward-looking statements set forth in this report and should be considered carefully in addition to the other information presented in this report. If any of the following risks actually occur, our business, results of operations or cash flows could be adversely affected. Our results of operations have varied widely in the past and could continue to vary significantly. In addition, our actual results may differ significantly from the results contemplated by the forward-looking statements. Accordingly, we believe that our results of operations in any given period may not be a good indicator of our future performance.

Market Acceptance. Our business depends upon broad market acceptance of laser vision correction by both doctors and patients in the United States and key international markets. Laser vision correction has penetrated less than 5% of the eligible United States population, and our profitability and continued growth will be largely dependent on increasing levels of market acceptance and procedure growth, especially with regard to our higher-priced CustomVue procedure, both in the United States and internationally. Although laser vision correction offers a more predictable outcome and more precise results than other surgical methods used to correct refractive disorders, it is not without risk. Potential complications and side effects include: post-operative discomfort, corneal haze (an increase in the light scattering properties of the cornea) during healing, glare/halos (undesirable visual sensations produced by bright lights), decreases in contrast sensitivity, temporary increases in intraocular pressure in reaction to procedure medication, modest fluctuations in refractive capabilities during healing, modest decrease in

Table of Contents

best corrected vision (i.e., with corrective eyewear), unintended over- or under-corrections, regression of effect, disorders of corneal healing, corneal scars, corneal ulcers, and induced astigmatism (which may result in blurred or double vision and/or shadow images). Some consumers may choose not to undergo laser vision correction because of these complications or more general concerns relating to its safety and efficacy or a resistance to surgery in general. Alternatively, some consumers may elect to delay undergoing laser vision correction surgery because they believe improved technology and/or methods of treatment will be available in the near future. Should either the ophthalmic community or the general population turn away from laser vision correction as an alternative to existing methods of treating refractive vision disorders, or if future technologies replaced laser vision correction, these developments could have a material adverse effect on our business, financial position and results of operations.

Patents and Intellectual Property Disputes. Our business is dependent on the enforceability and the validity of our United States and foreign patents. We own over 210 United States and foreign patents and have more than 230 patent applications pending. In the past, our patents have been challenged on several fronts and we have asserted our patents against competitors. Generally, these proceedings centered on whether infringement of the patents had occurred, and on the validity or enforceability of the patents. While all of these proceedings have now been resolved, we may assert our patents against competitors in the future. If our patents were found to be invalid or unenforceable (or in the event that parties against whom VISX asserted patent infringement were found not to be infringing our patents) in any future proceedings, our ability to collect license fees from the parties to the litigation or from other sellers or users of laser vision correction equipment in the United States may suffer and our revenues may decline. In addition, other companies own United States and foreign patents covering methods and apparatus for performing corneal surgery with ultraviolet lasers. If we were accused of infringing such competitors' patents and found to have infringed such patents, we could be subject to significant monetary liability and enjoined from distributing our products. Any one of these results could harm our business. See Item 1 Legal Proceedings of Part II of this report for additional information regarding legal proceedings involving VISX.

Competition. Intense competition in the laser vision correction industry could result in the loss of customers, an inability to attract new customers, or a decrease in prices for our products. The medical device and ophthalmic laser industries are subject to intense competition and technological change. Not only does laser vision correction compete with more traditional vision correction options such as eyeglasses and contact lenses, it also competes with other technologies and surgical techniques such as corneal implants, intraocular lenses, and surgery using different types of lasers. In addition, the market for laser vision correction systems has become increasingly competitive in recent years as a result of FDA approval of several laser systems. The VISX STAR System competes with products marketed or under development by other laser and medical equipment manufacturers, many of which have greater financial and other resources. Competitors may offer laser systems at a lower price, may price their laser systems as part of a bundle of products or services, may develop procedures that involve a lower per procedure cost, or may offer products perceived as preferable to the VISX STAR System. In addition, medical companies, academic and research institutions and others could develop new therapies, including new medical devices or surgical procedures, for the conditions targeted by VISX, which therapies could be more medically effective and less expensive than laser vision correction, and could potentially render laser vision correction obsolete. Any such developments could have a material adverse effect on our business, financial position and results of operations.

Unfavorable Side Effects. The possibility of long-term side effects and adverse publicity regarding laser correction surgery could seriously harm our business. Laser vision correction is a relatively new procedure. Consequently, there is no long-term follow-up data beyond ten years that might reveal additional complications or unknown side effects. Any future reported side effects, other adverse events or unfavorable publicity involving patient outcomes resulting from the use of laser vision correction

Table of Contents

systems manufactured by VISX or any participant in the laser vision correction market, may have a material adverse effect on our business, financial position, and results of operations.

Economic Conditions. Because laser vision correction is not subject to reimbursement from third-party payors such as insurance companies or government programs, the cost of laser vision correction is typically borne by individuals directly. Accordingly, weak or uncertain economic conditions may cause individuals to be less willing to incur the procedure cost associated with laser vision correction as was evidenced by our decline in revenues from 2002 compared to 2001 and from 2001 compared to 2000. A decline in economic conditions could have a material adverse effect on our business, financial position, and results of operations.

Third Party Financing Entities. We have relationships with third party financing entities that purchase our products directly and subsequently lease and/or sell these products to our end-user customers, or provide financing directly to customers who purchase our products directly from us. Should any third party financing entity or entities fail or refuse to pay us in a timely manner or at all, it could negatively affect our cash flows and could have a material adverse effect on our business, financial position and results of operations. In fact, DVI, which provided equipment purchase financing to our customers, entered into Chapter 11 bankruptcy proceedings in August 2003, and as a result, we recorded bad debt expense to increase our reserve for doubtful accounts to cover the entire \$2.3 million of accounts receivables then outstanding from DVI.

Significant Customers. A significant portion of our revenues has been derived from sales to TLC Vision Corporation (TLC) formed in May 2002 through the merger of Laser Vision Centers, Inc. and TLC Laser Eye Centers, Inc., both long-term customers of ours. TLC and its operating subsidiaries accounted for 17% and 12% of total revenues in the third quarter of 2003 and 2002, respectively, and 16% and 15% of total revenues in the first nine months of 2003 and 2002, respectively. At September 30, 2003 and December 31, 2002, TLC represented 23% and 22% of accounts receivable, respectively. Should we lose a significant customer or if anticipated sales to a significant customer do not materialize, our business, financial position and results of operations may suffer. In addition, should a significant customer become unable to pay balances owed, we would have to increase our charges for bad debt expense which could have a material adverse effect on our financial position and results of operations.

Fixed Short-Term Expenses. Because our expenses are relatively fixed in the short term, our earnings will decline if we do not meet our projected sales. Any shortfall in revenues below expectations would likely have an immediate impact on our earnings per share, which could adversely affect the market price of our common stock. Our operating expenses, which include sales and marketing, research and development, and general and administrative expenses, are based on our expectations of future revenues and are relatively fixed in the short term. Accordingly, if revenues fall below expectations, we will not be able to reduce our spending rapidly in response to such a shortfall.

Governmental Regulation. We are subject to extensive governmental regulation, which increases our costs and could prevent us from selling our products. Government regulation includes inspection of and controls over research and development, testing, manufacturing, safety and environmental controls, efficacy, labeling, advertising, promotion, pricing, record keeping, the sale and distribution of pharmaceutical products and samples and electronic records and electronic signatures. In the United States, we must obtain FDA approval or clearance for each medical device that we market. The FDA approval process is typically lengthy and expensive, and approval is never certain. Products distributed outside of the United States are also subject to government regulation, which may be equally or more demanding. Our new products could take a significantly longer time than we expect to gain regulatory approval and may never gain approval. If a regulatory authority delays approval of a potentially significant product, our market value and operating results may decline. Even if the FDA or another

Table of Contents

regulatory agency approves a product, the approval may limit the indicated uses for a product, may otherwise limit our ability to promote, sell and distribute a product or may require post-marketing studies. If we are unable to obtain regulatory approval of our products, we will not be able to market these products, which would result in a decrease in our sales. Currently, we are actively pursuing approval for a number of our products from regulatory authorities in a number of countries, including, among others, the United States, countries in the European Union and Japan. Continued growth in our sales and profits will depend, in part, on the timely and successful introduction and marketing of some or all of these products.

The clinical trials required to obtain regulatory approvals are complex and expensive and their outcomes are uncertain. We incur substantial expense for, and devote significant time to, clinical trials but cannot be certain that the trials will ever result in the commercial sale of a product. We may suffer significant setbacks in clinical trials, even after earlier clinical trials showed promising results. Any of our products may produce undesirable side effects that could cause us or regulatory authorities to interrupt, delay or halt clinical trials of a product candidate. We, the FDA, or another regulatory authority may suspend or terminate clinical trials at any time if they or we believe the trial participants face unacceptable health risks.

Noncompliance with applicable United States regulatory requirements can result in fines, injunctions, penalties, mandatory recalls or seizures, suspensions of production, denial or withdrawal of pre-marketing approvals, recommendations by the FDA against governmental contracts and criminal prosecution. The FDA also has authority to request repair, replacement, or the refund of the cost of any device we manufacture or distribute. Regulatory authorities outside of the United States may impose similar sanctions for noncompliance with applicable regulatory requirements.

Taxes. We operate throughout the United States and, consequently, are subject to various federal, state and local taxes, including sales, income, payroll, unemployment, property, franchise, capital and use tax on our operations, payroll, assets and services. Although we believe we have adequate provisions and accruals in our financial statements for tax liabilities, we cannot predict the outcome of all past and future tax assessments. If any taxing authority determines we owe amounts for taxes greater than we expect, our earnings may be negatively affected.

New Products May Not Be Commercially Viable. While we devote significant resources to research and development, our research and development may not lead to new products that achieve commercial success. The research and development process is expensive, prolonged, and entails considerable uncertainty. Development of a new medical device, from discovery through testing and registration to initial product launch, typically takes between three and seven years. Each of these periods varies considerably from product to product and country to country. Because of the complexities and uncertainties associated with ophthalmic research and development, products we are currently developing may not complete the development process or obtain the regulatory approvals required to market such products successfully. The products currently in our development pipeline may not be approved by regulatory entities and may not be commercially successful, and our current and planned products could be surpassed by more effective or advanced products.

International Operations. We face risks due to our reliance on sales in international markets. Our future success will depend in part on the continued expansion of our international sales and operations. In particular, during 2002, 2001, and 2000, we derived approximately 23%, 16% and 18%, respectively, of our revenues from sales to customers outside the United States. Our growing international presence exposes us to risks including:

the need for export licenses;

Table of Contents

unexpected regulatory requirements;

tariffs and other potential trade barriers and restrictions;

political, legal and economic instability in foreign markets;

longer accounts receivable cycles;

difficulties in managing operations across disparate geographic areas;

foreign currency fluctuations;

reduced or limited protection of our intellectual property rights in some countries; and

dependence on local distributors.

If one or more of these risks materialize, our sales to international customers may decrease and our costs may increase, which could negatively impact our revenues and operating results.

Product Liability Claims. We have and may become subject to product liability claims. We could be liable for injuries or damage resulting from use of the VISX STAR System or WaveScan System. In addition, a claim that an injury resulted from a defect in any VISX product, even if successfully defended, could damage our reputation. Although we possess insurance customarily obtained by businesses of our type (including insurance against product liability risks associated with the testing, manufacturing, and marketing of our products), product liability claims in excess of our insurance coverage could have a material adverse effect on our business, financial position, and results of operations.

Single Sources For Key Components. The manufacture of the VISX STAR System and WaveScan System is a complex operation involving numerous procedures. We depend on single and limited sources for several key components. If any of these suppliers were to cease providing components, we would be required to locate and contract with a substitute supplier. We could have difficulty identifying a substitute supplier in a timely manner or on commercially reasonable terms. If the production of our products, parts and services were interrupted or could not continue in a cost-effective or timely manner, our business, financial position, and results of operations, could be materially adversely affected.

Volatility of our Stock Price. The market price of our common stock has experienced fluctuations and is likely to fluctuate significantly in the future. Our stock price can fluctuate for a number of reasons, including:

announcements about us or our competitors;

results or settlements of any litigation;

quarterly variations in operating results;

the introduction or abandonment of new technologies or products;

changes in product pricing policies by us or our competitors;

Table of Contents

changes in earnings estimates by analysts or changes in accounting policies; and

economic changes and political uncertainties.

In addition, stock markets have experienced significant price and volume volatility in recent years. This volatility has had a substantial effect on the market prices of securities of many public companies for reasons frequently unrelated or disproportionate to the operating performance of the specific companies. In addition, the securities of many medical device companies, including VISX, have historically been subject to extensive price and volume fluctuations that may affect the market price of their common stock. If these broad market fluctuations continue, they may adversely affect the market price of our common stock.

Confidentiality Agreements. We rely on confidentiality agreements to protect our proprietary technology. We protect our proprietary technology, in part, through confidentiality and nondisclosure agreements with employees, consultants and other parties. Our confidentiality agreements with employees and consultants generally contain standard provisions requiring those individuals to assign to us, without additional consideration, inventions conceived or reduced to practice by them while employed or retained by us, subject to customary exceptions. If any of our employees, consultants or others breach these confidentiality agreements our competitors may learn of our trade secrets.

New Technologies. If we fail to keep pace with advances in our industry or fail to develop new methods of vision correction, customers may not buy our products and our revenue may decline. We must be able to manufacture and effectively market those products and persuade a sufficient number of eye care professionals to use the new products we introduce. Sales of our existing products may decline rapidly if a new product is introduced by one of our competitors or if we announce a new product that, in either case, represents a substantial improvement over our existing products. A decrease in procedure volume may also occur if consumers elect to delay undergoing laser vision correction surgery because they believe improved technology and/or methods of treatment will be available in the near future.

Antitakeover Provisions in Our Charter Documents. In 2000, we adopted a stockholder rights plan. The presence of this plan could make it more difficult for a third party to engage in a takeover attempt, even a takeover attempt in which the potential purchaser offers to pay a per share price greater than the current market price for our common stock. In addition, the presence of the plan could delay or impede the removal of incumbent directors. These provisions may also impact the amount of interest investors have in our business.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

There were no material changes during the nine months ended September 30, 2003 to our exposure to market risk for changes in interest rates and foreign currency exchange rates.

Item 4. Controls and Procedures

VISX management, including the Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this quarterly report. Based on that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that, as of the end of the period covered by this quarterly report, the disclosure controls and procedures are effective in ensuring that all material information required to be filed in this quarterly report has been made known to them in

Table of Contents

a timely fashion. There were no changes in VISX's internal control over financial reporting that occurred during the period covered by this report that have materially affected, or are likely to materially affect, VISX's internal control over financial reporting.

Part II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we have been involved in a variety of legal proceedings. For a complete description of legal proceedings, see our annual report on Form 10-K for the year ended December 31, 2002 and our quarterly reports on Form 10-Q for the quarters ended March 31, 2003 and June 30, 2003. During the quarter ended September 30, 2003, there were no material developments with respect to such previously existing proceedings and no new material proceedings not previously disclosed.

Item 5. Other Information

Non-Audit Services

In accordance with Section 10A(i)(2) of the Securities Exchange Act of 1934, as added by Section 202 of the Sarbanes-Oxley Act of 2002, VISX is responsible for disclosing the non-audit services approved by VISX's Audit Committee to be performed by KPMG LLP, VISX's independent auditor. Non-audit services are defined in the law as services other than those provided in connection with an audit or a review of the financial statements of VISX. The non-audit services approved by the Audit Committee in the third quarter are considered by VISX to be audit-related services that closely relate to the financial audit process. Each of the services has been approved in accordance with a pre-approval from the Audit Committee's Chairman pursuant to delegated authority by the Audit Committee.

During the quarterly period covered by this filing, the Committee approved additional engagements of KPMG LLP for the following non-audit service: tax return preparation, non-audit accounting services, and tax matter consultations concerning federal and state taxes.

Qualified Trading Plans

On August 1, 2003, August 15, 2003, and June, 13, 2003, Elizabeth H. Davila, Chairman of the Board and Chief Executive Officer, John F. Runkel, Jr., Vice President, General Counsel, and Donald L. Fagen, Vice President, Global Sales, respectively, each entered into separate written trading plans (each a Plan) relating to future sales of their shares of VISX common stock.

Each Plan is intended to comply with Rule 10b5-1 of the Securities Exchange Act of 1934, as amended, and provides for monthly stock sales if the prevailing market price is above specified levels. Within broad constraints, these plans mean that the market may begin to see more frequent sales of the holdings of these individuals. In the future, other officers and directors may choose to adopt similar plans.

Item 6. Exhibits and Reports on Form 8-K

a) *Exhibits.*

Table of Contents

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

b) *Reports on Form 8-K.*

VISX filed reports on Form 8-K during the period covered by this report, as follows:

- (1) Report on Form 8-K filed on July 23, 2003 under Item 12 (Results of Operations and Financial Condition) covering VISX's second quarter 2003 financial results.

SIGNATURES

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.

VISX, Incorporated

(Registrant)

November 10, 2003
(Date)

/s/Elizabeth H. Dávila

Elizabeth H. Dávila
Chairman of the Board and
Chief Executive Officer

November 10, 2003
(Date)

/s/Timothy R. Maier

Timothy R. Maier
Executive Vice President and
Chief Financial Officer (*principal
financial officer*)

November 10, 2003
(Date)

/s/Derek A. Bertocci

Derek A. Bertocci
Vice President, Controller (*principal
accounting officer*)

Table of Contents

Exhibit Index

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