VISX INC
Form 10-Q
November 08, 2004

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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, 2004

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	**06-1161793**
(State or other Jurisdiction of Incorporation or Organization)	*(IRS Employer Identification No.)*
3400 Central Expressway, Santa Clara, California	**95051-0703**
(Address of principal executive offices)	*(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 22, 2004: 49,609,981

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PART I. FINANCIAL INFORMATION

Item 1. Unaudited Condensed Consolidated Interim Financial Statements

VISX, INCORPORATED AND SUBSIDIARIES

CONDENSED CONSOLIDATED INTERIM BALANCE SHEETS
(In thousands, except share and per share amounts)

	September 30, 2004 (unaudited)	December 31, 2003 (unaudited)
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 10,113	$ 24,895
Short-term investments	110,933	61,181
Accounts receivable, net of allowance for doubtful accounts of $3,845 and $4,195, respectively	28,986	27,432
Inventories	17,149	11,219
Deferred tax assets and prepaid expenses	25,894	20,477
Total current assets	193,075	145,204
Property and Equipment, net	4,078	3,851
Long-Term Deferred Tax and Other Assets	13,168	14,908
	$ 210,321	$ 163,963
LIABILITIES AND STOCKHOLDERS EQUITY		
Current Liabilities:		
Accounts payable	$ 4,957	$ 3,442
Accrued liabilities and other current liabilities	38,583	34,722
Total current liabilities	43,540	38,164
Stockholders Equity:		
Common stock: $.01 par value, 180,000,000 shares authorized; 64,990,089 shares issued at September 30, 2004 and December 31, 2003, respectively	650	650
Additional paid-in capital	199,584	201,108
Treasury stock, at cost 15,411,259 and 16,295,297 shares, at	(248,042)	(258,218)

September 30, 2004 and December 31, 2003, respectively		
Accumulated other comprehensive income	79	341
Retained earnings	214,510	181,918
Total stockholders equity	166,781	125,799
Total liabilities and stockholders equity	$ 210,321	$ 163,963

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

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VISX, INCORPORATED AND SUBSIDIARIES

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2004	**2003**	**2004**	**2003**
Revenues:				
License and other revenues	$27,169	$23,494	$ 89,887	$ 63,235
System revenues	6,480	11,136	19,859	28,743
Service and parts revenues	5,022	4,638	15,706	13,709
Total revenues	38,671	39,268	125,452	105,687
Costs and Expenses:				
Cost of license and other revenues	763	1,009	2,607	2,548
Cost of system revenues	4,808	11,752	16,913	27,316
Cost of service and parts revenues	3,710	3,574	11,336	10,685
Selling, general and administrative	9,268	10,538	29,500	30,846
Research, development and regulatory	5,766	4,814	16,261	13,649
Total costs and expenses	24,315	31,687	76,617	85,044
Income From Operations	14,356	7,581	48,835	20,643
Interest and other income	607	369	1,393	3,130
Income Before Provision For Income Taxes	14,963	7,950	50,228	23,773
Provision for income taxes	(3,671)	(3,085)	(17,636)	(9,334)
Net Income	$11,292	$ 4,865	$ 32,592	$ 14,439
Earnings Per Share				
Basic	$ 0.23	$ 0.10	$ 0.66	$ 0.29

Diluted	$ 0.22	$ 0.10	$ 0.64	$ 0.28
Shares Used For Earnings Per Share				
Basic	49,525	48,065	49,066	49,816
Diluted	50,971	50,132	50,739	50,995

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

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VISX, INCORPORATED AND SUBSIDIARIES

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Nine months ended September 30,	
	2004	**2003**
Cash flows from operating activities:		
Net income	$ 32,592	$ 14,439
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	6,752	6,296
Tax benefit from exercise of stock options	7,500	
Provision for doubtful accounts receivable	146	2,044
Increase (decrease) in cash flows from changes in operating assets and liabilities:		
Accounts receivable	(1,707)	(2,200)
Inventories	(14,474)	(5,792)
Deferred tax assets and prepaid expenses	(2,839)	5,088
Long-term deferred tax and other assets	2,380	2,505
Accounts payable	1,515	(337)
Accrued liabilities and other current liabilities	3,848	(6,900)
Net cash provided by operating activities	35,713	15,143
Cash flows from investing activities:		
Capital expenditures	(1,664)	(1,349)
Cash paid for acquisition of patents and technology assets		(5,900)
Purchase of available for sale securities	(85,782)	(45,853)
Proceeds from maturities of available for sale securities	35,793	86,800
Net cash provided by (used in) investing activities	(51,653)	33,698
Cash flows from financing activities:		
Proceeds from issuance of common stock	17,547	2,535
Repurchases of common stock	(16,395)	(63,000)

Net cash provided by (used in) financing activities	1,152	(60,465)
Effect of exchange rate changes on cash and cash equivalents	6	27
Net decrease in cash and cash equivalents	(14,782)	(11,597)
Cash and cash equivalents, beginning of period	24,895	37,687
Cash and cash equivalents, end of period	$ 10,113	$ 26,090
Supplemental Cash Flow Information:		
Cash paid for income taxes:	$ 12,795	$ 2,238
Non-cash investing activities:		
Inventory transferred to deferred costs under operating leases	$ 8,534	$ 5,454

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

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VISX, INCORPORATED AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS
September 30, 2004
(Unaudited)

1. Significant Accounting Policies:

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 in the United States. Please read our 2003 Annual Report on Form 10-K to gain a more complete understanding of these interim financial statements. The results of operations for the three and nine months ended September 30, 2004 are not necessarily indicative of the results for the entire year or any other period.

We included in these interim financial statements all adjustments (consisting primarily of normal recurring adjustments) that in our opinion are necessary to present fairly our results for the interim periods. Our interim financial statements have not been audited.

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, and are unaudited.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net Income	$11,292	$ 4,865	$32,592	$14,439
Basic Earnings Per Share				
Income available to common stockholders	$11,292	$ 4,865	$32,592	$14,439
Weighted average common shares outstanding	49,525	48,065	49,066	49,816
Basic Earnings Per Share	$ 0.23	$ 0.10	$ 0.66	$ 0.29
Diluted Earnings Per Share				
Income available to common stockholders	$11,292	$ 4,865	$32,592	$14,439
Weighted average common shares outstanding	49,525	48,065	49,066	49,816
Dilutive potential common shares from stock options	1,446	2,067	1,673	1,179

Weighted average common shares and dilutive potential common shares	50,971	50,132	50,739	50,995
Diluted Earnings Per Share	$ 0.22	$ 0.10	$ 0.64	$ 0.28

Options to purchase 2,138,000 and 1,996,000 shares with a weighted average exercise price of $33.92 and $34.97 during the three month periods ended September 30, 2004 and 2003, respectively, were excluded from the computation of diluted EPS because the options exercise prices were greater than the average market price of our common stock during these periods and would have been anti-dilutive.

Options to purchase 2,092,000 and 4,795,000 shares with a weighted average exercise price of $34.27 and $24.46 during the nine month periods ended September 30, 2004 and 2003, respectively, were

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excluded from the computation of diluted EPS because the options exercise prices were greater than the average market price of our common stock during these periods and would have been anti-dilutive.

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 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,**	
		2004	**2003**	**2004**	**2003**
Net Income	As Reported	$11,292	$ 4,865	$32,592	$14,439
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects		(2,109)	(1,906)	(6,340)	(6,071)
Net Income	Pro Forma	$ 9,183	$ 2,959	$26,252	$ 8,368
Basic Earnings Per Share	As Reported	$ 0.23	$ 0.10	$ 0.66	$ 0.29
	Pro Forma	0.19	0.06	0.54	0.17
Diluted Earnings Per Share	As Reported	$ 0.22	$ 0.10	$ 0.64	$ 0.28
	Pro Forma	0.18	0.06	0.52	0.17

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:

	Three Months Ended September 30,	**Nine Months Ended September 30,**

	2004	2003	2004	2003
Expected life of options (in years)	5.58	4.78	5.27	4.35
Expected life of ESPP rights (in years)	1.25	1.25	1.25	1.25
Volatility for options	69%	74%	71%	75%
Volatility for ESPP rights	58%	60%	59%	60%
Risk free interest rate for options	3.45%	2.32%	2.99%	2.46%
Risk free interest rate for ESPP rights	1.91%	1.63%	1.72%	1.61%
Dividend yield	0.0%	0.0%	0.0%	0.0%

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The weighted average fair value of options granted under our stock option plans during the three and nine month periods ended September 30, 2004 was $13.17 and $12.30, respectively. The weighted average fair value per share of options granted under the ESPP during the three and nine month periods ended September 30, 2004 was $5.13 and $4.69, respectively.

The weighted average fair value of options granted under our stock option plans during the three and nine month periods ended September 30, 2003 was $12.92 and $6.34, respectively. The weighted average fair value per share of options granted under the ESPP during the three and nine month periods ended September 30, 2003 was $3.88 and $3.63, respectively.

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.

2. Segment Reporting:

Segments. Statement of Financial Accounting Standards No. 131, Disclosures About Segments of an Enterprise and Related Information, (SFAS No. 131) established standards for reporting information about operating segments in financial statements. Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker, or chief operating decision making group, in deciding how to allocate resources and in assessing performance. Our CEO is our chief operating decision maker. Our business is focused on one operating segment, products and procedures to improve people s vision with laser vision correction. All of our revenues and profits are generated through the sale, licensing, and service of products for this one segment.

Export Revenues. Export revenues accounted for 16% and 15% of total revenues for the three month periods ended September 30, 2004 and September 30, 2003 respectively, and 16% and 17% of total revenues for the nine month periods ended September 30, 2004 and September 30, 2003 respectively. We did not generate export revenues to any country that equaled or exceeded 10% of our total revenues for the three and nine month periods ended September 30, 2004 and September 30, 2003. In the following table we have presented our export revenues by geographic region (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	**2003**	**2004**	**2003**
Europe	1,834	2,258	5,372	5,738
Americas (excluding the United States)	1,006	1,060	2,784	2,876
Asia and Other	3,391	2,760	11,849	9,796
	$6,231	$6,078	$20,005	$18,410

Substantially all of our long-term assets are located in the United States.

Major Customers. A significant portion of our revenues are derived from sales to TLC Vision Corporation (TLC). Sales to TLC accounted for 15% and 17% of total revenues for the three month periods ended September 30, 2004 and 2003, respectively. For the nine month periods ended September 30, 2004 and 2003 TLC accounted for 18% and 16% of total revenues, respectively. TLC accounted for 22% of our total receivables at both September 30, 2004 and December 31, 2003. Additionally, Taiwan Hwa-In Corporation accounted for 13% of our total receivables at September 30, 2004.

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3. Inventories

Components of inventories are as follows (in thousands):

	September 30, 2004	December 31, 2003
	(Unaudited)	
Raw materials and subassemblies	$10,563	$ 7,786
Work-in-process	2,810	1,321
Finished goods	3,776	2,112
	$17,149	$11,219

4. Comprehensive Income (unaudited, in thousands):

We report components of comprehensive income in our annual consolidated statements of stockholders equity. Components of comprehensive income (unaudited, in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net income	$11,292	$4,865	$32,592	$14,439
Other comprehensive income (net of related tax effects):				
Increase (decrease) in accumulated unrealized holding gains on available-for-sale securities	39	(81)	(237)	(1,413)
Change in accumulated foreign currency translation adjustment	(5)	86	(25)	77
Comprehensive income	$11,326	$4,870	$32,330	$13,103

5. Warranty Obligations

Warranty obligations are included in accrued liabilities. Changes in product warranty obligations for the periods ended September 30, 2004 and 2003 are as follows (unaudited, in thousands):

	Three Months Ended	Nine Months Ended

	September 30,		September 30,	
	2004	2003	2004	2003
Balance as of the beginning of the period	$1,376	$ 1,663	$ 1,779	$ 1,963
Expense accrued for new warranties	159	1,700	487	3,098
Cost of services provided	(423)	(1,028)	(1,154)	(2,726)
Balance as of the end of the period	$1,112	$ 2,335	$ 1,112	$ 2,335

6. 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

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agreement that is superseded by the acquisition. These assets are included in other assets and are being amortized to cost of system revenues at the greater of actual usage or the estimated useful life of five years.

7. Stockholders Equity

On April 4, 2001, our Board of Directors authorized a new 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 7.8 million shares cumulatively on the open market through September 30, 2004 at a total cost of $106.8 million. Accordingly, 2.2 million shares remain available as of September 30, 2004 for repurchase under the Board of Directors April 2001 authorization. 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 $63.0 million, all of which were purchased during the quarter ended June 30, 2003.

8. Income Tax Provision

Our effective tax rate in the third quarter of 2004 was 24.5% as compared to 38.8% in the third quarter of 2003. The decrease was primarily attributable to the release of certain tax accruals due to differences between our original estimates of certain prior year income tax expenses and revisions based on the elimination of contingencies from prior year tax returns. This led to a benefit of approximately $2.2 million in the three months ended September 30, 2004.

9. New Accounting Pronouncements

In December 2003, the FASB revised Interpretation No. 46 (FIN 46), Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51 which it had originally issued in January 2003. As revised, FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. As revised, application of FIN 46 is required for interests in special-purpose entities for periods ending after December 15, 2003. Application for all other types of entities covered by FIN 46 is required in financial statements for periods ending after March 15, 2004. The adoption of FIN 46 as revised, did not have a material impact on our financial position or results of operations.

In May 2003, the FASB issued Statement of Financial Accounting Standards No. 150 (SFAS 150), Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity . SFAS 150 requires that certain financial instruments, which under previous guidance were accounted for as equity, must now be accounted for as liabilities. The financial instruments affected include mandatory redeemable stock, certain financial instruments that require or may require the issuer to buy back some of its shares in exchange for cash or other assets and certain obligations that can be settled with shares of stock. SFAS 150 is effective for all financial instruments entered into or modified after May 31, 2003, and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003, although certain aspects have been delayed pending further clarifications. The Company currently does not have any financial instruments that are within the scope of this statement.

In November 2003, the EITF reached an interim consensus on Issue No. 03-01, The Meaning of Other-Than-Temporary Impairment and its Application to Certain Investments to require additional disclosure requirements for securities classified as available-for-sale or held-to-maturity for fiscal years ending after December 15, 2003. In March 2004, the EITF reached a final consensus on this Issue, to provide additional guidance which companies must follow in determining whether investment securities have an impairment which should be considered other-than-temporary. The guidance is applicable for reporting periods beginning after June 15, 2004. The Company does not expect the adoption under the final consensus to have a significant impact on the carrying value of its investments.

10. Reclassifications

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

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: our belief that our CustomVue procedure represents a new standard in laser vision correction; 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 may increase consumer acceptance of laser vision correction surgery; our belief that we have the largest installed base of laser vision correction systems in place worldwide and that we have approximately 60% market share for procedures performed in the United States; our plan to continue to generate cash from our ongoing business in 2004; the possibility that we may repurchase shares of our common stock through the remainder of 2004; our belief there will not be a near-term change in our level of capital expenditures; our belief that a decline in economic conditions in the United States could result in a decline in the number of laser vision correction procedures performed; our belief that our revenue and profit for the balance of 2004 will to improve compared to 2003; our belief that operating expenses will increase compared to 2003; our target of increasing operating margins to in excess of 35% of revenues; our expectation that we will continue to generate cash from operations; our belief that procedure growth was negatively impacted by the hurricanes that affected the eastern United States in the third quarter; our belief that our license revenue will improve for the balance of 2004 as compared to 2003; our belief that the lack of long-term follow-up studies, media coverage of selected unfavorable outcomes, and economic uncertainties may impact interest in laser vision correction; our belief that system revenue for the remainder of 2004 will be less than the comparable period of 2003; our projection that research and development expense in the fourth quarter of 2004 will be comparable to the fourth quarter of 2003; our belief that operations will generate cash in 2004 at a level equal to or greater than in 2003; our belief that cash from operations will exceed cash required to fund our working capital and capital equipment needs during the coming twelve months; and our belief that the estimates and judgments made regarding future events in connection with the preparation of our financial statements are reasonable. The following discussion and analysis should be read together with our Condensed Consolidated Financial Statements and the Notes to those statements included elsewhere in this Quarterly Report on Form 10-Q. This discussion contains forward-looking statements based on our current expectations, assumptions, estimates and projections about us and our industry. These forward-looking statements include, but are not limited to, statements concerning risks and uncertainties. The risks and uncertainties include the potential reduction in demand for our equipment and upgrades, and the potential decline in demand for procedures caused by the weakness in the economy, consumer confidence and stock markets in the United States in recent years. Our actual results could differ materially from those indicated in these forward-looking statements as a result of certain factors, as more fully described in the Factors Affecting Future Operating Results section of this Management s Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this Quarterly Report on Form 10-Q. We undertake no obligation to update publicly any forward-looking statements for any reason, even if new information becomes available or other events occur in the future.

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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. Our primary operations are in Santa Clara, CA.

Our products require FDA approval in the United States and comparable regulatory agency approvals in other countries. Our approvals in the United States and key markets worldwide for laser vision correction cover most types of refractive vision disorders including:

- Nearsightedness;
- Farsightedness; and
- Astigmatism.

Our CustomVue procedure is also available for all of these refractive vision disorders in most international markets. In May 2003, we obtained FDA approval for our new CustomVue procedure for nearsightedness and astigmatism.

We sell products worldwide and generate the majority of our revenues and cash through license fees charged for the performance of laser vision correction procedures using the VISX STAR Excimer Laser System (VISX STAR System). The license fee charged for a particular procedure depends on whether the procedure is performed in the United States or internationally, and the type of procedure involved. In the United States, we charge a license fee for our standard procedure and a license fee for our CustomVue procedure that is more than twice the amount charged for our standard procedure. Additionally, we charge a standard price of $10 per procedure for treatment cards. Internationally, for our standard procedure we charge a small price per procedure for the treatment card. For our CustomVue procedure we charge a significantly higher price per procedure.

We believe our CustomVue procedure, which requires use of a WaveScan System, represents a new standard in laser vision correction. It enables doctors to identify, measure, and correct imperfections in a patient s eye much more precisely than ever before, thus creating the potential for patients to experience better vision than is possible with glasses or contact lenses.

We believe we have the largest installed base of laser vision correction systems, with over 1300 VISX STAR Systems in place worldwide. We also believe we have approximately 60% market share for procedures performed in the United States. According to MarketScope, we have held at least 60% market share since 1997.

License revenues comprise the majority of our revenues and carry a gross profit margin of approximately 97%. License revenues also generated approximately 90% of our gross profit dollars in the three and nine month periods ended September 30, 2004. Such revenues are predominantly derived from license fees

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from our United States customers. License revenues grew 16% and 42% in the three and nine month periods ended September 30, 2004 compared with the corresponding periods in 2003. We evaluate this aspect of our business by tracking the following:

- The number of procedures sold;
- Trends in procedure sales, including conversion rates from standard to CustomVue procedures; and
- Market share for VISX and its competitors.

Any increase in license fee revenue that results from either an increase in the amount charged for a particular procedure or from an increase in overall procedure volume directly impacts our net income. As a result, our management team is focused on activities that will (i) accelerate the market s acceptance of, and conversion to, our CustomVue procedure; (ii) enable VISX to maintain or gain market share; and (iii) increase the laser vision correction market in general. Progress on any one of these fronts offers the potential for growth in our license revenue.

We manage our expenses closely and plan to continue to generate cash from our ongoing business operations in 2004. Historically, our primary non-operating use of cash has been to repurchase shares of our common stock. We bought 0.8 million shares of stock in the first nine months of 2004 and may repurchase additional shares through the remainder of 2004. We will also continue to investigate areas where we can expand our business. This could result in using cash for the acquisition of technology or a business. Our capital expenditures have been in the range of $2.4 million to $4.0 million per year in the past five years. We do not expect to exceed this level of expenditures in 2004. We have no long term debt.

Looking to the remainder of 2004, our business is highly leveraged on procedure volume and the conversion to CustomVue procedures. A number of factors, the most material of which are set forth below, could impact our success in 2004 and beyond:

- Market acceptance of laser vision correction. Increased acceptance of laser vision correction by both doctors and patients in the United States and key international markets is essential for our continued growth. Laser vision correction has penetrated approximately 6% 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. We expect that ongoing technical advances, such as the CustomVue procedure, will enhance the quality of patients vision and may also increase consumer acceptance of laser vision correction surgery.

- Our ability to obtain additional FDA approvals. We continue to expand the list of FDA approved indications that can be treated by our systems. As we receive approvals for additional types and ranges of refractive disorders from the FDA, the pool of eligible laser vision correction candidates increases, thereby expanding the potential for growth in procedures, CustomVue adoption and license revenue.

- Our competition. Competition in the laser vision correction market is intense which creates pricing pressure on our products. Additionally, most of our competitors have greater resources and a stronger international market presence. As a result, the competition to obtain procedure market share is intense.

The United States economy. We have always charged a license fee for procedures sold in the United States. Therefore, it remains our most significant market for license revenue. As such, economic conditions in the United States impact our license revenue more than global economic conditions. Industry analysts have tracked procedure volume in the United States against economic indicators such as consumer confidence and have noted a correlation between consumer confidence and the number of laser vision correction procedures performed per quarter. A decline in economic conditions in the United States could result in a decline in the number of laser vision correction procedures performed.

We believe our revenue and profit for the balance of 2004 will improve as compared to 2003 as a result of various factors including higher CustomVue adoption and improvements in the United States economy. For 2004, we anticipate that operating expenses will increase compared to 2003 with a target of increasing our operating margins to in excess of 35% of revenues. We expect to continue to generate cash from operations.

Results of Operations

	Three Months Ended September 30,			**Nine Months Ended September 30,**		
($ 000 s)	**2004**	**2003**	**Change**	**2004**	**2003**	**Change**
License and other revenues	$27,169	$23,494	*16%*	$ 89,887	$ 63,235	*42%*
Percent of total revenues	*70.3%*	*59.8%*		*71.7%*	*59.8%*	
System revenues	6,480	11,136	*(42)%*	19,859	28,743	*(31)%*
Percent of total revenues	*16.7%*	*28.4%*		*15.8%*	*27.2%*	
Service and parts revenues	5,022	4,638	*8%*	15,706	13,709	*15%*
Percent of total revenues	*13.0%*	*11.8%*		*12.5%*	*13.0%*	
Total revenues	$38,671	$39,268	*(2)%*	$125,452	$105,687	*19%*

License and other revenues

License and other revenues increased $3.7 million, to $27.2 million for the three months ended September 30, 2004, from $23.5 million for the three months ended September 30, 2003. The increase was primarily attributable to increased adoption of our CustomVue procedure and 4% procedure growth in the United States. We believe that procedure growth was negatively impacted by the hurricanes that affected the Eastern United States in the third quarter of 2004. We introduced the CustomVue procedure in June 2003 in the United States and sell the product for more than double the price of our standard procedure. License and other revenues increased $26.7 million, to $89.9 million for the nine months ended September 30, 2004, from $63.2 million for the nine months ended September 30, 2003. The increase was primarily attributable to increased adoption of our CustomVue procedure and procedure growth in the United States. In the United States, CustomVue procedures represented approximately 35% of the procedure orders in the nine month period ended September 30, 2004.

We believe that our license and other revenues will improve for the balance of 2004 as compared to 2003. The decision to have laser vision correction surgery is influenced by many factors. The procedure is elective and generally not covered by medical insurance; therefore it competes with many types of purchases for consumers discretionary spending. Perceptions about safety and effectiveness of the procedure are additional considerations. The lack of long-term follow-up studies of the procedure combined with media coverage of selected unfavorable outcomes may contribute to uncertainty and delay by some potential consumers. Economic uncertainties may also impact the interest in laser vision

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correction. As such, we cannot accurately predict when, or to what extent changes in the economy and technology will impact our license and other revenues.

System revenues

System revenues comprise sales and leases of the following equipment:

VISX STAR Systems;

WaveScan Systems; and

Upgrades

System revenues decreased by $4.6 million to $6.5 million for the three months ended September 30, 2004 from $11.1 million for the three months ended September 30, 2003. System revenues decreased by $8.8 million to $19.9 million for the nine months ended September 30, 2004 from $28.7 million for the nine months ended September 30, 2003. The decrease in both periods is primarily due to fewer WaveScan System sales in 2004 as compared to 2003 as at least 80% of our United States customers now have one or more WaveScan Systems.

More VISX STAR Systems were shipped during the nine months ended September 30, 2004 as compared to the comparable period of 2003. However a greater number were shipped under operating leases during the nine months ended September 30, 2004. Under operating leases revenue is generally recognized over the term of the agreement.

The market for laser systems remains competitive. Pricing pressures in 2004 have contributed to the decrease in system revenues as we experienced lower per unit pricing on laser sales in the nine months ended September 30, 2004 compared with the comparable period of 2003. MarketScope estimates that VISX is the leader in the worldwide market with approximately 30% of worldwide laser placements.

For these reasons, we believe that system revenue for the remainder of 2004 will be less than the comparable period in 2003.

Service and parts revenues

Service and parts revenues increased by $0.4 million to $5.0 million for the three months ended September 30, 2004 from $4.6 million for the three months ended September 30, 2003. Service and parts revenues increased by $2.0 million to $15.7 million for the nine months ended September 30, 2004 from $13.7 million for the nine months ended September 30, 2003. Service and parts revenues for the three and nine month periods ended September 30, 2004 were higher than the comparable periods for 2003 primarily due to higher procedure volumes and the resultant higher revenues derived from customers that purchased service on a per procedure basis.

	Three Months Ended September 30,			**Nine Months Ended September 30,**		
($ 000 s)	**2004**	**2003**	**Change**	**2004**	**2003**	**Change**
Cost of license and other revenues	$ 763	$ 1,009	*(24)%*	$ 2,607	$ 2,548	*2%*
Percent of related revenues	*2.8%*	*4.3%*		*2.9%*	*4.0%*	
Cost of system revenues	4,808	11,752	*(59)%*	16,913	27,316	*(38)%*
Percent of related revenues	*74.2%*	*105.5%*		*85.2%*	*95.0%*	

Cost of service and parts revenues	3,710	3,574	*4%*	11,336	10,685	*6%*
Percent of related revenues	*73.9%*	*77.1%*		*72.2%*	*77.9%*	
Selling, general and administrative	9,268	10,538	*(12)%*	29,500	30,846	*(4)%*
Percent of total revenues	*24.0%*	*26.8%*		*23.5%*	*29.2%*	

($ 000 s)	Three Months Ended September 30, 2004	2003	Change	Nine Months Ended September 30, 2004	2003	Change
Research, develop. and regulatory	5,766	4,814	*20%*	16,261	13,649	*19%*
Percent of total revenues	*14.9%*	*12.3%*		*13.0%*	*12.9%*	

Cost of license and other revenues

Cost of license and other revenues decreased $0.2 million to $0.8 million for the three months ended September 30, 2004 from $1.0 million for the three months ended September 30, 2003. Cost of license and other revenues increased $0.1 million, to $2.6 million for the nine months ended September 30, 2004, from $2.5 million for the nine months ended September 30, 2004. The overall increase in the gross profit percentage is due to lower costs associated with the production of custom cards when compared to the related period in 2003.

Cost of system revenues

Cost of system revenues decreased $7.0 million to $4.8 million for the three months ended September 30, 2004 from $11.8 million for the three months ended September 30, 2003. Cost of system revenues decreased $10.4 million to $16.9 million for the nine months ended September 30, 2004 from $27.3 million for the nine months ended September 30, 2003. The decreases in cost of system revenues were due primarily to the decrease of revenues from the sales of lasers, upgrades and WaveScan Systems. In addition, a greater number of systems were shipped under operating leases during the three and nine months ended September 30, 2004 versus the comparable periods of 2003. Under operating leases, costs are recognized in proportion to the revenues recognized over the term of the agreement. Cost of system revenues in the first and second quarters of 2004 were overstated by $0.1 million and $0.3 million, respectively. The third quarter includes a $0.4 million adjustment to correct these overstatements. The amount of such charges were not material to our consolidated results of operations in the three months ended March 31, 2004, June 30, 2004 and September 30, 2004 or the nine months ended September 30, 2004.

Cost of service and parts revenues

Cost of service and parts revenues increased $0.1 million to $3.7 million for the three months ended September 30, 2004 from $3.6 million for the three months ended September 30, 2003. The overall gross profit margin increased to 26% in the three months ended September 30, 2004 compared to 23% in the corresponding period of 2003 as labor costs are relatively fixed and parts usage does not typically increase linearly with procedure volume. Costs of service and parts revenues increased $0.6 million to $11.3 million for the nine months ended September 30, 2004 from $10.7 million for the nine months ended September 30, 2003. Cost of service and parts revenues increased due to a larger installed base of products in the United States.

Selling, general and administrative expenses

Selling, general and administrative expenses decreased by $1.2 million to $9.3 million for the three months ended September 30, 2004 from $10.5 million for the three months ended September 30, 2003. The change reflects primarily the following items:

In the third quarter of 2003, DVI Inc. (DVI), which provided equipment purchase financing to VISX customers, entered into Chapter 11 bankruptcy proceedings. Bad debt expense decreased by $1.8 million in the third quarter of 2004 as compared to the third quarter of 2003 primarily due to the increase in reserves in 2003 to cover the entire $2.3 million of accounts receivable then outstanding from DVI;

United States marketing costs decreased by $0.3 million primarily due to a reduction in professional media costs in 2004 compared to those incurred in 2003 associated with the launch of CustomVue in 2003;

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Increased selling, general and administrative costs primarily attributable to higher personnel related costs of $0.6 million; and

Administrative expenses increased $0.3 million primarily due to the costs of compliance with the provisions of the Sarbanes Oxley Act.

Selling, general and administrative expenses decreased by $1.3 million to $29.5 million for the nine months ended September 30, 2004 from $30.8 million for the nine months ended September 30, 2003. Decreased bad debt expenses and legal expenses were offset by higher commission expenses due to higher revenues and increased administrative spending to reflect the cost of compliance with the provisions of the Sarbanes Oxley Act.

For the remainder of 2004, our current plan for operations includes:

A net increase in legal expenses in 2004 since the fourth quarter of 2003 benefited from the non-recurring receipt of insurance reimbursements of legal expenses totaling approximately $3.1 million; and

A modest decrease in selling general and administrative spending as compared to the fourth quarter of 2003.

Research and development and regulatory expenses

Research and development and regulatory expenses increased by $1.0 million to $5.8 million for the three months ended September 30, 2004 from $4.8 million for the three months ended September 30, 2004. Research and development and regulatory expenses increased by $2.7 million to $16.3 million for the nine months ended September 30, 2004 from $13.6 million for the nine months ended September 30, 2003. These increases relate primarily to our ongoing focus on next generation technologies and developments for laser vision correction, including:

System advancements;

New methods for correcting vision disorders including further indications (such as hyperopia and high myopia) for our CustomVue treatment; and

Continued research and clinical trials for treatment of presbyopia.

We project that research and development expense in the fourth quarter of 2004 will be comparable to the level of expenditures in the fourth quarter of 2003.

Interest and other income

Interest and other income increased by $0.2 million to $0.6 million for the three months ended September 30, 2004 from $0.4 million for the three months ended September 30, 2003. Slightly higher yields on our portfolio balances contributed to the increase in interest income compared to the third quarter of 2003. Interest income decreased by $1.7 million to $1.4 million for the nine months ended September 30, 2004 from $3.1 million for the nine months ended September 30, 2003. In 2003 we sold available-for sale securities to repurchase shares of VISX stock. This led to a $1.2 million realized gain on available for sale securities. The holding gains were previously recorded in accumulated other comprehensive income, and were recognized in interest and other income upon realization in 2003.

Income tax provision

Our effective tax rate in the third quarter of 2004 was 24.5% as compared to 38.8% in the third quarter of 2003. The decrease was primarily attributable to the release of certain tax accruals due to differences between our original estimates of certain prior year income tax expenses and revisions based on the elimination of contingencies from prior year tax returns.

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This led to a benefit of approximately $2.2 million in the three months ended September 30, 2004.

Liquidity and Capital Resources

Cash, cash equivalents and short-term investments (cash) and working capital were as follows (in thousands):

	September 30, 2004	December 31, 2003
Cash, cash equivalents and short-term investments	$121,046	$ 86,076
Working capital	149,535	107,040
Stockholders equity	166,781	125,799

Our cash, cash equivalents and short-term investments consist principally of money market funds and bonds issued by the United States government, government sponsored enterprises and corporations. 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. Gains and losses are recognized when realized in the consolidated statements of operations.

Cash, cash equivalents and short-term investments were $121.0 million at September 30, 2004, an increase of $35.0 million compared with December 31, 2003. It was impacted principally by:

Positive cash flow from operating activities of $35.7 million;

Proceeds from issuance of common stock related to employee participation in employee stock programs generating $17.5 million;

Repurchases of 0.8 million shares of stock at a total cost of $16.4 million; and

Capital expenditures of $1.7 million.

Operating activities generated $35.7 million in cash in the nine months ended September 30, 2004 up from $15.1 million provided in the nine months ended September 30, 2003. In the first nine months of 2004, we:

Generated $47.0 million of cash from net operations plus non-cash related expenses;

Increased Inventory by $14.5 million primarily to support the increase in system sales and anticipated shipments of the Fourier upgrade and Iris Registration, and;

Accrued and other current liabilities increased by $3.8 million due primarily to the deferral of revenue associated with operating lease arrangements.

Net cash used in investing activities was $51.7 million in the nine months ended September 30, 2004 down from $33.7 million net cash provided in the nine months September 30, 2003. The principal movements in cash used in investing activities in the first nine months of 2004 were due to the investments in, and maturities of, short-term investments. Net cash provided by investing activities in the first nine months of 2003 consisted primarily of the investments in, and maturities of, short-term investments offset by a payment of $5.9 million for acquired patents and technology from 20/10 Perfect Vision Optische Gerate GmbH.

Cash provided by financing activities was $1.2 million in the nine months ended September 30, 2004 as compared to $60.5 million cash used in the nine months ended September 30, 2003. This was primarily due to more cash being provided by the exercise of options than used in the repurchase of shares in 2004 as compared to 2003 when the reverse was true.

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 7.8 million shares on the open market cumulatively through September 30, 2004, at a total cost of $106.8 million. Accordingly, 2.2 million shares remain available as of September 30, 2004 for repurchase under the Board of Directors April 2001 authorization. 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 $63.0 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, 2004, we did not have any borrowings outstanding, nor any credit agreements.

Our normal credit terms granted to customers are net 30 to net 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 continue to generate cash in 2004 at a level equal to or greater than in 2003. We believe this will exceed cash required to fund our working capital and capital equipment needs during the coming twelve months. In addition, we have $121.0 million in cash, cash equivalents and short-term investments as of September 30, 2004 to provide for unforeseen contingencies and to support strategic objectives including the development or acquisition of new technologies and our Stock Repurchase Program.

Critical Accounting Policies

We follow accounting principles generally accepted in the United States (GAAP) in preparing our financial statements. As part of this process, 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. We believe our most critical accounting policies, estimates and judgments include the following:

Revenue Recognition

We are required to ensure that collectibility is reasonably assured before we recognize revenue. Accordingly, we evaluate our customers for credit worthiness and only recognize revenue if we believe that we have reasonable assurance that amounts will be collected. Where we are unable to assess with reasonable assurance that amounts will be collected, we defer revenue recognition until the payments are

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received. This is occasionally the case with customers who have recently set themselves up in business and typically where the customer is thinly capitalized.

Accounts Receivable

At the end of each accounting period, we estimate the reserve necessary for accounts receivable 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 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. Our allowance for doubtful accounts at September 30, 2004 and December 31, 2003 as a percentage of gross accounts receivable was 11.7% and 13.3%, respectively. At September 30, 2004, a one-percentage point deviation in our allowance for doubtful accounts as a percentage of accounts receivable would have resulted in an increase or decrease in expense of approximately $0.4 million.

Inventories

Adjustments to the carrying value of inventory for excess and obsolete items are based, in part, on our estimate of demand over the following 6 months. This estimate, though based on our historical experience and consideration of other relevant factors, (such as the current economic climate), is subject to some uncertainty. Amounts charged to income for excess and obsolete inventory for the three and nine month periods ending September 30, 2004 and September 30, 2003 as a percentage of total revenues in those periods, were all less than 1.0%. To date, our estimates have been materially accurate. We do not expect either our methodology or the accuracy of our estimates to change significantly in the future unless there are any major changes in our business model, our operating environment or the economy, or the ongoing development of our technology.

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, although historically, the amounts we have paid out have been materially similar to the amounts that we have accrued. 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 pending or threatened legal actions against us 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.

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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 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 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 approximately 6% of the eligible United States population, and our profitability and growth will be largely dependent on increasing levels of market acceptance and procedure growth, especially with regard to our higher-priced CustomVue procedure. Although we believe 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 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 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 delay or prevent market acceptance of laser vision correction, which would 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 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.

Government Regulation. We are subject to extensive government 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 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.

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.

Clinical Trials. 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.

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 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 lower the prices they charge for procedures, 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.

Procedure Market Share. MarketScope estimated that as at June 30, 2004 we were the leader in the United States procedures market with a market share of over 60%. Because of this position, all of our competitors target us and our market share in order to grow their own revenues. We can give no assurance that we will be able to maintain or grow our existing market share and we may, in fact, be required to incur considerable expenditures in order to maintain or increase that market share. Should our procedure market share decline, it could have a material adverse effect on our business, financial position, and results of operations as well as the market price of our common stock.

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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 especially in the United States, could result in a decline in the number of laser vision correction procedures performed and could have a material adverse effect on our business, financial position, and results of operations.

Significant Customers. A significant portion of our revenues is derived from sales to TLC Vision Corporation (TLC). Sales to TLC accounted for 15% and 17% of total revenues for the three month periods ended September 30, 2004 and 2003, respectively. For the nine month periods ended September 30, 2004 and 2003 TLC accounted for 18% and 16% of total revenues, respectively. TLC accounted for 22% of our total receivables at both September 30, 2004 and December 31, 2003. Additionally, Taiwan Hwa-In Corporation accounted for 13% of our total receivables at September 30, 2004. 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 business, financial position and results of operations.

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, as well as new methods of vision correction that we introduce such as our CustomVue procedure. 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 or methods of treatment will be available in the near future.

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.

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 200 United States and foreign patents and have more than 200 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 our historical 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

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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 could suffer and our revenues could 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.

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.

Litigation. In the past, we have been involved in a number of legal proceedings, some of which have resulted in significant legal expenses and settlement costs. In the future, we may become involved in additional legal proceedings that, regardless of their outcome or validity, could lead to additional expenses being incurred and diversion of our management s resources.

Section 404 Compliance. We must comply with the rules promulgated under Section 404 of the Sarbanes-Oxley Act of 2002 (Section 404) by December 31, 2004. Rules describing the requirements for our auditors to be able to attest to our compliance under Section 404 were adopted in June, 2004. Currently, there is no precedent or proven method for compliance with Section 404, and our management must exercise significant judgment in our effort to do so. As a result of this uncertainty, we cannot be certain that we will comply with the requirements of Section 404 in a timely manner. If we do not, public perception of our internal controls could be damaged, causing our financial results to suffer and our stock price to decline.

International Operations. We face risks due to our reliance on sales in international markets. Sales to customers outside the United States represented 16% of our total revenues for the three and nine months ended September 30, 2004 and 15% and 17% of our total revenues for the three and nine months ended September 30, 2003. To date, all of our sales have been denominated in United States dollars. Our international presence exposes us to risks including:

- the need for export licenses;
- 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.

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Distributors. Internationally, we sell our products through distributors. If we fail to maintain our existing distribution channels or develop additional channels in the future, our ability to sell products internationally could be impaired and our business harmed.

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 any remaining exposure on the $2.3 million of accounts receivables then outstanding from DVI.

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.

*Acquisitions of Businesses or Technology***.** We have acquired technology assets and may need to continue to do so to retain our competitive position within the marketplace. If we acquire businesses, new products or technologies in the future, we may be required to amortize significant amounts of identifiable intangible assets and we may record significant amounts of goodwill that will be subject to annual testing for impairment. If we consummate one or more significant future acquisitions in which the consideration consists of stock or other securities, our existing stockholders ownership could be significantly diluted. If we were to proceed with one or more significant future acquisitions in which the consideration included cash, we could be required to use a substantial portion of our available cash. Additionally, such an acquisition could have a substantial impact on our business, our financial position and our results of operations.

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.

Key Personnel. The success of our business depends on the efforts and abilities of our senior management and other key personnel. We do not have long term employment agreements with any of our key personnel. The loss of any of our executive officers or other key employees could result in significant disruption to our ongoing operations and hurt our business. Additionally, our inability to attract new senior executives and key personnel could significantly impact our business results.

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 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;
- 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.

Proprietary Information and Inventions Agreements. We protect our proprietary technology, in part, through proprietary information and inventions agreements with employees, consultants and other parties. These 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 agreements our competitors may learn of our trade secrets.

Changes to the Accounting for Stock Options. The Financial Accounting Standards Board has issued a draft Financial Accounting Standard which includes proposed rule changes requiring expensing of stock options. Currently, we include such expenses on a pro forma basis in the notes to our annual financial statements in accordance with accounting principles generally accepted in the United States but do not include stock option expense for employee options in our reported financial statements. If accounting standards are changed to require us to expense stock options, our reported earnings will decrease significantly and our stock price could decline.

Exercising of stock options. As of September 30, 2004, there were an aggregate of 5,580,448 shares of our common stock issuable upon exercise of outstanding vested stock options. If these stock options are exercised, the total number of our traded shares will increase and this could adversely impact our earnings per share.

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.

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Item 3. Quantitative and Qualitative Disclosures about Market Risk

There were no material changes during the nine months ended September 30, 2004 in our exposure to market risk for changes in interest rates and foreign currency exchange rates.

Our exposure to market risk for changes in interest rates relates primarily to our investment portfolio. We do not use derivative financial instruments and our investment portfolio to manage our interest rate risk, foreign currency risk or for any other purpose. We invest in high-credit quality issuers and, by policy, limit the amount of credit exposure to any one issuer. As stated in our policy, we ensure the safety and preservation of our invested principal funds by limiting default risk, market risk and reinvestment risk. We mitigate default risk by investing in safe and high-credit quality securities and by constantly positioning our portfolio to respond appropriately to a significant reduction in a credit rating of any investment issuer, guarantor or depository. The portfolio includes only marketable securities with active secondary or resale markets to ensure portfolio liquidity.

Item 4. Controls and Procedures

VISX management, including the Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of 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 (the Evaluation Date). Based on that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that, as of the Evaluation Date, the 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 a timely fashion.

There have been no significant changes in internal controls over financial reporting (as defined in Rule 13a-15(f)) during the three months ended September 30, 2004 that materially affected, or are reasonably likely to materially affect, our internal controls 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, 2003. During the quarter ended September 30, 2004, there were no material developments with respect to such previously existing proceedings and no new material proceedings not previously disclosed.

Item 2. Changes in Securities, Use of Proceeds and Issuer Purchases of Equity Securities

The following table contains information regarding repurchases of our common stock during the quarter:

Period	Total Number of Shares Purchased (1)	Average Price Per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (2)	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
July 1 through July 31, 2004	20,000	$ 21.37	20,000	2,209,200
August 1 through August 31, 2004	40,000	18.86	40,000	2,169,200
September 1 through September 30, 2004				2,169,200
Total	60,000	$ 19.70	60,000	

(1) Shares have only been repurchased through publicly announced programs. All repurchases were open-market purchases.

(2) On April 4, 2001 our Board of Directors authorized the repurchase of up to 10 million shares of our common stock. We have repurchased 7.8 million shares cumulatively through September 30, 2004 under the Board of Directors April 2001 authorization. Number of shares does not include an additional 3.5 million shares of our common stock approved for repurchase by our Board of Directors on May 28, 2003, all of which were repurchased during the quarter ended June 30, 2003.

Unless terminated earlier by resolution of our Board of Directors, each share repurchase program expires when we have repurchased all shares authorized for repurchase thereunder.

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Item 5. Other Information

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 first 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.

Item 6. Exhibits and Reports on Form 8-K

a) *Exhibits*.

31.1 Certification of the Chief Executive Officer pursuant to Securities Exchange Act Rules 13a-15(e) and 15d-15(e) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

31.2 Certification of the Chief Financial Officer pursuant to Securities Exchange Act Rules 13a-15(e) and 15d-15(e) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

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

32.1 Certification of the 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 8-K filed on July 21, 2004 under Item 12 (Disclosure of Results of Operations and Financial Condition) to reference and furnish as an exhibit a press release dated July 21, 2004 announcing our VISX s second quarter financial results.

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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 8, 2004	/s/ Elizabeth H. Dávila
	Elizabeth H. Dávila Chairman of the Board and Chief Executive Officer
November 8, 2004	/s/ Derek A. Bertocci
	Derek A. Bertocci Senior Vice President and Chief Financial Officer *(principal financial officer)*
November 8, 2004	/s/ Martyn J. Webster
	Martyn J. Webster Controller *(principal accounting officer)*

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