CHOLESTECH CORPORATION
Form 10-Q
February 05, 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 December 26, 2003

[ ] 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: 000-20198

CHOLESTECH CORPORATION

(Exact name of registrant as specified in its charter)

California	**94-3065493**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

3347 Investment Boulevard, Hayward, CA 94545
(Address of principal executive offices) (Zip Code)

(510) 732-7200
(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for 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 [ ]

As of January 29, 2004, 14,034,423 shares of the registrant s common stock were outstanding.

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PART I - FINANCIAL INFORMATION

ITEM 1. CONDENSED FINANCIAL STATEMENTS

CHOLESTECH CORPORATION
CONDENSED BALANCE SHEETS
(in thousands)

	December 26, 2003 (unaudited)	March 28, 2003(1)
Assets		
Current assets:		
Cash and cash equivalents	$ 9,974	$ 8,747
Marketable securities	12,957	4,776
Accounts receivable, net	6,359	5,195
Inventories, net	6,157	6,806
Note receivable	250	250
Prepaid expenses	1,670	1,989
Deferred tax assets	2,100	2,100
Total current assets	39,467	29,863
Property and equipment, net	8,207	7,491
Long-term investments	8,226	12,558
Long-term deferred tax assets	3,388	2,100
Total assets	$ 59,288	$ 52,012
Liabilities and Shareholders Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 10,855	$ 3,971
Accrued payroll and benefits	3,781	3,173
Other liabilities	106	140
Total current liabilities	14,742	7,284
Contingencies (note 8)		
Shareholders equity:		
Common stock, no par value; 25,000,000 shares authorized; 13,836,782 and 14,001,401 shares issued and outstanding at March 28, 2003 and December 26, 2003, respectively	83,744	82,242
Accumulated other comprehensive income	126	73
Accumulated deficit	(39,324)	(37,587)
Total shareholders equity	44,546	44,728
Total liabilities and shareholders equity	$ 59,288	$ 52,012

(1) The information in this column was derived from the Company s audited consolidated financial statements as of the fiscal year ended March 28, 2003.

See Notes to Condensed Financial Statements

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CONDENSED STATEMENTS OF OPERATIONS
(in thousands, except per share data)
(unaudited)

	Thirteen Weeks Ended		Thirty-nine Weeks Ended	
	Dec. 26, 2003	Dec. 27, 2002	Dec. 26, 2003	Dec. 27, 2002
Revenue	$13,363	$12,022	$40,434	$35,061
Cost of goods sold	6,166	5,569	17,328	14,847
Gross profit	7,197	6,453	23,106	20,214
Operating expenses:				
Sales and marketing	3,388	2,862	9,465	8,684
Research and development	754	632	2,360	1,885
General and administrative	2,238	2,122	6,411	5,096
Other operating costs			250	
Litigation and other related	7,356	112	7,786	196
Total operating expenses	13,736	5,728	26,272	15,861
Income (loss) from operations	(6,539)	725	(3,166)	4,353
Interest and other income, net	62	97	271	314
Income (loss) before provision for income taxes	(6,477)	822	(2,895)	4,667
Provision (benefit) for income taxes	(2,526)	32	(1,129)	187
Income (loss) from continuing operations	(3,951)	790	(1,766)	4,480
Loss from sale of discontinued operations		(4,282)		(4,282)
Gain (loss) from discontinued operations	8	(252)	47	(1,453)
Tax provision (benefit) from discontinued operations	3	(55)	18	(103)
Income (loss) from discontinued operations	5	(197)	29	(1,350)
Net loss	$ (3,946)	$ (3,689)	$ (1,737)	$ (1,152)
Income (loss) from continuing operations per share:				
Basic	$ (0.28)	$ 0.06	$ (0.13)	$ 0.33
Diluted	$ (0.28)	$ 0.06	$ (0.13)	$ 0.32
Income (loss) from discontinued operations per share:				
Basic	$ 0.00	$ (0.33)	$ 0.00	$ (0.42)
Diluted	$ 0.00	$ (0.33)	$ 0.00	$ (0.40)
Net loss per share:				
Basic	$ (0.28)	$ (0.27)	$ (0.13)	$ (0.09)

Diluted	$ (0.28)	$ (0.27)	$ (0.13)	$ (0.08)
Shares used to compute income per share:				
Basic	13,988	13,619	13,880	13,522
Diluted	13,988	13,761	13,880	14,169

See Notes to Condensed Financial Statements

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CONDENSED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Thirty-nine Weeks Ended	
	Dec. 26, 2003	**Dec. 27, 2002**
Cash flows from operating activities:		
Net loss	$ (1,737)	$ (1,152)
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	1,963	1,894
Change in allowance for losses on accounts receivable	72	10
Change in inventory reserve	160	30
Stock acceleration charge		(72)
Change in allowance for sales returns		43
Loss from sale of discontinued operations		4,282
Changes in assets and liabilities:		
Accounts receivable	(1,236)	(268)
Inventories	489	(827)
Prepaid expenses and other assets	319	(423)
Accounts payable and accrued expenses	6,884	1,010
Accrued payroll and benefits	608	336
Deferred tax assets	(1,288)	
Other liabilities	(34)	(15)
Net cash provided by operating activities	6,200	4,848
Cash flows from investing activities:		
Sales and maturities of marketable securities	38,893	37,431
Purchases of marketable securities	(42,689)	(38,373)
Purchases of property and equipment	(2,679)	(2,162)
Net cash used in investing activities	(6,475)	(3,104)
Cash flows from financing activities:		
Purchase of treasury stock		(104)
Issuance of common stock	1,502	2,659
Net cash provided by financing activities	1,502	2,555
Net decrease in cash and cash equivalents	1,227	4,299
Cash and cash equivalents at beginning of period	8,747	8,800
Cash and cash equivalents at end of period	$ 9,974	$ 13,099

See Notes to Condensed Financial Statements

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NOTES TO CONDENSED FINANCIAL STATEMENTS

1. Interim Results

The interim unaudited financial information of Cholestech Corporation (the Company) is prepared in conformity with accounting principles generally accepted in the United States of America. The financial information included herein has been prepared by management, without audit by independent auditors, and should be read in conjunction with the audited consolidated financial statements contained in the Annual Report on Form 10-K for the fiscal year ended March 28, 2003. The information furnished includes all adjustments and accruals consisting only of normal recurring accrual adjustments that are, in the opinion of management, necessary for a fair presentation of results for the interim periods. Certain information or footnote disclosure normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America has been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission.

The interim results are not necessarily indicative of the results of operations for the full fiscal year ending March 26, 2004.

2. Reclassifications

Certain financial statement items have been reclassified to conform to the current period s format. These reclassifications had no impact on previously reported results of operations.

3. Sale of WellCheck

On December 23, 2002, the Company completed the sale of certain assets and the assignment of certain obligations of its wholly owned subsidiary WellCheck Inc. (WellCheck) to ImpactHealth.com, Inc. (ImpactHealth). Information presented in the financial statements for prior periods have been adjusted to reflect WellCheck as Discontinued Operations. The Company received a payment of $50,000 plus accrued interest from ImpactHealth during January 2004 pursuant to the secured promissory note in the aggregate amount of $250,000 (the Note) received as a result of the sale. On December 23, 2003 the Company and ImpactHealth negotiated a revision in the structure of the Note payments terms for the remaining $200,000 due, which provides for quarterly payment installments of $50,000 each and an interest rate of 6.5% per annum.

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Revenues and losses of the Company s discontinued operations for the thirteen and thirty-nine weeks ended December 26, 2003 and December 27, 2002 (in thousands of dollars) were as follows:

	Thirteen Weeks Ended		Thirty-nine Weeks Ended	
	Dec. 26, 2003	Dec. 27, 2002	Dec. 26, 2003	Dec. 27, 2002
Revenues	$ 0	$ 790	$ 0	$ 1,472
Income (loss) before provision for income taxes	8	(252)	47	(1,453)
Income tax provision (benefit)	3	(55)	18	(103)
Net income (loss)	$ 5	$ (197)	$ 29	$ (1,350)

Contingent sales proceeds, including TEAMS royalty and performance remuneration, will be recognized as earned as a component of discontinued operations.

4. Derivative Financial Instruments

At December 26, 2003, in order to minimize the impact of exchange rate fluctuations with the purchase of its GDX and related products, the Company had outstanding forward contracts to purchase £478,000 for approximately $750,000. The open contracts mature at various dates through May 17, 2004 and hedge certain forecasted inventory purchases denominated in the British Pound Sterling. The unrealized gain on the forward contracts at December 26, 2003 was $96,000, all of which is expected to be reclassified to earnings within the next 12 months. There was no gain or loss recorded in the period from hedge ineffectiveness or from forecasted transactions no longer expected to occur.

5. Earnings Per Share

Basic earnings per share (EPS) is computed by dividing net income by the weighted average number of common shares outstanding during the period. Diluted earnings per share gives effect to all potential common stock outstanding during a period, if dilutive.

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A reconciliation of the basic and diluted earnings per share calculations follows:

	Thirteen Weeks Ended		Thirty-nine Weeks Ended	
	Dec. 26, 2003	Dec. 27, 2002	Dec. 26, 2003	Dec. 27, 2002
(in thousands, except per share data)				
Income				
Income (loss) from continuing operations	$ (3,951)	$ 790	$ (1,766)	$ 4,480
Income (loss) from discontinued operations	5	(4,479)	29	(5,632)
Net loss	$ (3,946)	$ (3,689)	$ (1,737)	$ (1,152)
Shares				
Basic	13,988	13,619	13,880	13,522
Effect of dilutive securities		142		647
Diluted	13,988	13,761	13,880	14,169
Per share continuing operations:				
Basic	$ (0.28)	$ 0.06	$ (0.13)	$ 0.33
Effect of dilutive securities	0.00	0.00	0.00	(0.01)
Diluted	$ (0.28)	$ 0.06	$ (0.13)	$ 0.32
Per share discontinued operations:				
Basic	$ 0.00	$ (0.33)	$ 0.00	$ (0.42)
Effect of dilutive securities	0.00	0.00	0.00	0.02
Diluted	$ 0.00	$ (0.33)	$ 0.00	(0.40)
Per share net loss				
Basic	$ (0.28)	$ (0.27)	$ (0.13)	$ (0.09)
Effect of dilutive securities	0.00	0.00	0.00	0.01
Diluted	$ (0.28)	$ (0.27)	$ (0.13)	$ (0.08)

As of December 26, 2003, options to purchase 2,237,368 shares of common stock were considered anti-dilutive because of the loss from continuing operations. As of December 27, 2002, options to purchase 1,627,046 shares of common stock were considered anti-dilutive because the respective exercise prices were greater than the average fair market value of the common stock.

6. Stock-Based Compensation

The Company accounts for its stock-based compensation plans in accordance with Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* as amended by SFAS No. 148, *Accounting for Stock-Based Compensation-Transition and Disclosure*. As permitted under SFAS No. 148, the Company uses the intrinsic value-based method of Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, to account for its employee stock-based compensation plans. Under APB Opinion No. 25, compensation expense is based on the difference, if any, on the date of grant, between the fair value of the Company s common shares and the exercise price of the option. Compensation costs for stock options, if any, are realized ratably over the vesting period.

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If compensation costs for the Company s stock option and stock purchase plans had been determined based on the fair market value of the options at the grant dates, as prescribed in SFAS No. 123, the Company s net loss and net loss per share would have been as follows:

	Thirteen Weeks Ended		Thirty-nine Weeks Ended	
	Dec. 26, 2003	Dec. 27, 2002	Dec. 26, 2003	Dec. 27, 2002
(in thousands, except per share data)				
Net loss as reported	$(3,946)	$(3,689)	$(1,737)	$(1,152)
Deduct total stock-based employee compensation expense determined under fair value based method for all awards	742	603	2,168	1,678
Pro forma net loss	$(4,688)	$(4,292)	$(3,905)	$(2,830)
Net loss per share:				
Basic				
As reported	$ (0.28)	$ (0.27)	$ (0.13)	$ (0.09)
Pro forma	$ (0.34)	$ (0.32)	$ (0.28)	$ (0.21)
Diluted				
As reported	$ (0.28)	$ (0.27)	$ (0.13)	$ (0.08)
Pro forma	$ (0.34)	$ (0.31)	$ (0.28)	$ (0.20)

Such pro forma disclosure may not be representative of future compensation costs because options vest over several years and additional grants are anticipated to be made each year. The fair value of each stock option is estimated on the date of the grant using the Black-Scholes valuation model, with the following assumptions used for grants during the applicable periods:

	Thirteen Weeks Ended		Thirty-nine Weeks Ended	
	Dec. 26, 2003	Dec. 27, 2002	Dec. 26, 2003	Dec. 27, 2002
Risk free interest rate	1.06%	1.73%	1.05%	1.73%
Expected life	7 Years	7 Years	7 Years	7 Years
Expected volatility	90.78%	95.13%	90.78%	95.13%
Dividend yield	0.0%	0.0%	0.0%	0.0%

7. Recent Accounting Pronouncements

In May 2003, the Financial Accounting Standard Board (FASB) issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*. SFAS No. 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. This standard is effective for financial instruments entered into or modified after May 31, 2003. The Company adopted this standard and the adoption of this standard had no material impact on its financial statements.

In April 2003, the FASB issued SFAS No. 149, *Amendment of Statement 133 of Derivative Instruments and Hedging Activities.* SFAS No. 149 amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts. This standard is effective for contracts entered into or modified after June 30,

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2003. The Company adopted this standard and the adoption of this standard had no material impact on its financial statements.

8. Contingencies

On August 2, 2002, N.V. Euromedix (Euromedix) filed suit against the Company in the Commercial Court in Leuven, Belgium (No. F5700-02), seeking damages for the wrongful termination of an implied distribution agreement with the Company for Europe and parts of the Middle East. On November 7, 2002, the court dismissed the suit. On December 31, 2002, Euromedix filed suit against the Company in the Commercial Court in Leuven, Belgium (No. F8756-02), seeking damages in the amount of approximately ∈3.5 million for the wrongful termination of an implied distribution agreement with the Company for Europe and parts of the Middle East. A hearing was held on April 29, 2003 regarding certain procedural issues. In a judgment rendered on May 27, 2003, the court referred the complaint to the Constitutional Court before rendering a final decision. The court asked the Constitutional Court to render an opinion regarding certain constitutional issues related to the trademark infringement arguments the Company raised at the hearing. Hearings in the Constitutional Court were held on July 8, 2003 and September 9, 2003. The court has not yet rendered its opinion. The Company believes these claims are without merit and intends to continue to defend the claims vigorously.

On December 19, 2003, the Company entered into a settlement agreement and license agreement with Roche Diagnostics Corporation and Roche Diagnostics GmbH (Roche) in connection with ongoing patent infringement litigation. The settlement, which serves as the basis for the dismissal of all patent litigation between the parties on a worldwide basis, provides for the Company to make a $7 million payment to Roche, which the Company made on December 30, 2003. In addition, Roche agreed to grant an irrevocable, non-exclusive, worldwide license to the Company for its patents related to HDL cholesterol. As a part of this settlement, the Company will pay Roche an ongoing royalty that will be applied to only the HDL portion of cholesterol test cassettes sold by the Company. Additionally the settlement agreement provides a mechanism for resolving any future patent infringement disputes. The Company believes that any such dispute resolution will confirm that its new HDL cholesterol test cassette, currently under development, does not infringe Roche s patents. If however, upon the resolution of any such dispute it is ultimately determined that the Company s new HDL cholesterol test cassette is covered by Roche s patents, the Company will pay the same ongoing royalty. The parties have been in litigation in the United States District Court for the Southern District of Indiana, Germany, Belgium, Switzerland and Austria. Motions to dismiss have been filed in each of these jurisdictions in connection with the settlement. The one-time payment to Roche associated with this settlement agreement, along with legal and related expenses, is included as an expense in the Company s Condensed Statement of Operations.

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9. Comprehensive Loss

The Company s total comprehensive loss was as follows (in thousands):

	Thirteen Weeks Ended		Thirty-nine Weeks Ended	
	Dec. 26, 2003	Dec. 27, 2002	Dec. 26, 2003	Dec. 27, 2002
Net loss	$(3,946)	$(3,689)	$(1,737)	$(1,152)
Change in unrealized gain on investments, net	(10)	44	(100)	126
Change in future currency contracts	28	24	153	40
Total comprehensive loss	$(3,928)	$(3,621)	$(1,684)	$ (986)

10. Income Taxes

For the thirty-nine weeks ended December 26, 2003, the Company recorded a benefit for income taxes of $1.1 million, primarily resulting from the increase in the value of the net operating losses arising from the loss in the period.

Based on the Company s continued positive operating results, in the fourth quarter of fiscal 2003, the Company determined that it was increasingly likely that it would be able to realize a portion of its net operating loss carryforwards in future periods, thereby reducing taxes to be paid in those periods. As such, a valuation allowance of $4.2 million for deferred tax assets was released for the amount of net operating loss carryforwards expected to be utilized in fiscal 2004 and 2005. For the thirty-nine weeks ended December 27, 2002, the Company recorded a provision for income tax of $84,000, primarily resulting from the estimated alternative minimum tax, since the Company had significant federal net operating losses and both federal and California state tax credit carryforwards.

11. Warranties

The Company records an accrual for estimated warranty costs when revenue is recognized. Warranty costs cover the costs of repairing the LDX Analyzer and replacing defective single use test cassettes. The warranty period of the LDX Analyzer is one year and single use test cassettes are warranted for the shelf-life of the product. The warranty costs of the GDX Analyzer and test cartridges are the responsibility of the vendor. The Company has processes in place to estimate accruals for warranty exposure. The processes include estimated LDX Analyzer failure rates, costs to repair the analyzer and estimated replacement rates for single use test cassettes. Although the Company believes it has the ability to reasonably estimate warranty expenses, unforeseeable changes in factors impacting the estimate for warranty could occur and such changes could cause a material change in the Company s warranty accrual estimate. Such a change would be recorded in the period in which the change was identified. Changes in the

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Company s product warranty liability during the thirty-nine weeks ended December 26, 2003 were as follows (in thousands):

	Thirty-nine Weeks Ended Dec. 26, 2003
Balance at the beginning of the year	$ 116
Accruals and charges for warranty for the year	346
Cost of repairs and replacements	(356)
Balance at December 26, 2003	$ 106

ITEM 2. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Certain statements in this Quarterly Report on Form 10-Q are forward-looking statements within the meaning of federal securities laws. These statements relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our or our industry s actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by the forward-looking statements. These risks and other factors include those listed under Factors Affecting Future Operating Results and elsewhere in this Quarterly Report on Form 10-Q. In some cases, you can identify forward-looking statements by terminology such as may , will , should , expect , plan , anticipate , believe , estimate , predict , potential , continue or the negative of these terms or other comparable terminology. Forward-looking statements include, but are not limited to, the following statements: our expectation regarding the source of a majority of our future revenue; plans related to our long term growth strategy; the opportunities provided by recent legislative developments and potential FDA approvals; our expectation regarding future sales and marketing expenses, legal expenses and outside professional services expenses; our expected income from securities investments; the possible recognition of additional deferred tax benefits in future periods; the sufficiency of our cash, cash equivalents, marketable securities, cash flows and line of credit to satisfy our anticipated operating requirements and our defenses to legal proceedings and litigation matters. In evaluating these statements, you should specifically consider various factors, including the risks outlined under Factors Affecting Future Operating Results . These factors may cause our actual results to differ materially from any forward-looking statement.

Although we believe the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of these forward-looking statements. We are under no duty to update any of the forward-looking statements after the date of this Quarterly Report on Form 10-Q to conform our prior statements to actual results.

Overview

We develop, manufacture and market products that perform diagnostic testing at sites outside of traditional hospital and clinical laboratories to assist in assessing for risk of heart disease, diabetes and certain liver diseases and in the monitoring of therapy to treat those diseases. Currently, we manufacture

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and sell our Cholestech LDX® System (the LDX System) , which consists of an analyzer, a test cassette, a printer and accessories, and sell our Cholestech GDX System (the GDX System), which consists of an analyzer, a test cartridge and accessories.

Until December 2002, our subsidiary WellCheck conducted consumer testing within the United States to help assess the risk of heart disease and other diseases. Using the LDX System and its Test Event Activity Management Software (TEAMS), WellCheck collected test results and other patient data and aggregated that data for testing event sponsors use in marketing programs.

In December 2002, we completed the sale of certain assets and the assignment of certain obligations of WellCheck to ImpactHealth. We received a secured promissory note in the aggregate principal amount of $250,000 (the Note) due on the first anniversary of the issuance of the Note, the right to receive an additional $200,000 contingent upon the attainment of certain performance measures and a royalty per participant tested with TEAMS for three years after the date of the agreement. In addition, we entered into a three-year renewable supply agreement with ImpactHealth involving the purchase of the LDX System and single use test cassettes by ImpactHealth on an exclusive basis. We received a payment of $50,000 plus accrued interest from ImpactHealth during January 2004 pursuant to the Note. On December 23, 2003 we negotiated a change in the structure of the Note payment terms with ImpactHealth which provides for quarterly payment installments of $50,000 each and an interest rate of 6.5% per annum.

Today, we derive our revenue from sales of diagnostic products, test cassettes, test cartridges and related accessories. We began marketing and distributing the GDX System in July 2002. However, we expect that a substantial majority of our revenue will continue to be generated from sales of our LDX product for the foreseeable future.

In connection with our long term growth strategy, we plan to dedicate additional resources to sales and marketing to enhance our market penetration of the physician office laboratory market. We also plan to accelerate our research and development activities in order to introduce new products which can be utilized on our LDX Analyzer. In addition, we are investing a significant amount of capital to improve the efficiency of our manufacturing operations. We also intend to seek opportunities to acquire or distribute single use test cassettes or other products which can be sold through our established distribution channels.

On December 8, 2003, President Bush signed legislation that allows Medicare reimbursement for cholesterol and diabetes screening. This legislation should provide further opportunity, starting in calendar year 2005, for us to capitalize on the increasing need for testing in both the physician office laboratory and health promotion markets to assess risk for heart disease and diabetes in individuals. Further, a major class of cholesterol lowering medications called statins may be approved by the FDA for over the counter sales in the future, which could provide pharmacies with an incentive to conduct testing of patients in the pharmacy as part of a health awareness initiative and provide us with additional opportunities to market our products.

On December 19, 2003 we entered into a settlement agreement and license agreement with Roche Diagnostics Corporation and Roche Diagnostics GmbH (Roche) in connection with ongoing patent infringement litigation. The settlement, which serves as the basis for the dismissal of all patent litigation between the parties on a worldwide basis, provides for our company to make a $7 million payment to Roche, which we made on December 30, 2003. In addition, Roche agreed to grant an irrevocable, non-exclusive, worldwide license to us for its patents related to HDL cholesterol. As a part of this

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settlement, we will pay Roche an ongoing royalty, that we belive is reasonable, and will be applied to only the HDL portion of cholesterol test cassettes sold by us. Payments to Roche pursuant to this license agreement, as with any future royalty payments, will be charged to costs of good sold as they are incurred. Additionally the settlement agreement provides a mechanism for resolving any future patent infringement disputes. We believe that any such dispute resolution will confirm that our new HDL cholesterol test cassette, currently under development, does not infringe Roche s patents. If however, upon the resolution of any such dispute it is ultimately determined that our new HDL cholesterol test cassette is covered by Roche s patents, we will pay the same ongoing royalty. The one-time payment to Roche associated with this settlement agreement, along with legal and related expenses, is included as an expense in our Statement of Operations.

Results of Operations

In the following discussion of our results of operations, results related to the WellCheck segment have been reclassified to Discontinued Operations for both the current fiscal year and fiscal year 2003.

The following table sets forth our results of operations expressed as a percentage of total revenue. Our historical operating results are not necessarily indicative of the results for any future period.

	Thirteen Weeks Ended		Thirty-nine Weeks Ended	
	Dec. 26, 2003	Dec. 27, 2002	Dec. 26, 2003	Dec. 27, 2002
Revenue	100%	100%	100%	100%
Cost of goods sold	46	46	43	42
Gross profit	54	54	57	58
Operating expenses				
Sales and marketing	25	24	23	25
Research and development	6	5	6	5
General and administrative	17	18	16	15
Other operating costs			1	
Litigation and other related	55	1	19	
Total operating expenses	103	48	65	45
Income (loss) from operations	(49)	6	(8)	12
Interest and other income		1	1	1
Benefit for income taxes	(19)		(3)	
Income (loss) from continuing operations	(30)	7	(4)	13
Loss from discontinued operations	0	(37)	0	(16)
Net loss	(30)%	(31)%	(4)%	(3)%

Thirteen weeks ended December 26, 2003 and December 27, 2002
and
Thirty-nine weeks ended December 26, 2003 and December 27, 2002

Revenue. For the thirteen weeks ended December 26, 2003, revenue increased $1.4 million, or 11%, to $13.4 million from $12.0 million for the thirteen weeks ended December 27, 2002. Sales of single use test cassettes increased $2.1 million, or 24%, from $9.1 million for the thirteen weeks ended December 27, 2002 to $11.2 million for the thirteen weeks ended December 26, 2003. Revenue for our

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LDX analyzer decreased $460,000, or 35%, to $857,000 for the thirteen weeks ended December 26, 2003 from $1.3 million for the thirteen weeks ended December 27, 2002. Revenue for our GDX analyzer and related single use test cartridges decreased $327,000, or 38%, to $528,000 for the thirteen weeks ended December 26, 2003, from $855,000 for the thirteen weeks ended December 27, 2002. Sales of accessories decreased $65,000, or 8%, to $728,000 for the thirteen weeks ended December 26, 2003 from $793,000 for the thirteen weeks ended December 27, 2002.

For the thirteen weeks ended December 26, 2003, domestic revenue increased $1.3 million, or 13%, to $11.5 million from $10.2 million for the thirteen weeks ended December 27, 2002. Most of the domestic increase related to revenue from single use test cassettes, which increased 27%, while unit volume of single use test cassettes increased 26% from the prior year period. The increase in revenue was attributable to the continued adoption by physicians of the ATP III guidelines for treatment of high cholesterol, the increased number of CLIA waived laboratories and increased growth in the use of statin drugs, all of which resulted in an increased installed customer base of our LDX which generated higher demand for our single use test cassettes within our LDX installed customer base. This resulted in a 26% revenue increase in sales to the physician office laboratory market, which increased $1.6 million to $7.8 million during the thirteen weeks ended December 26, 2003, from $6.2 million for the thirteen weeks ended December 27, 2002. Additionally, revenue for our GDX analyzer and related single use test cartridges decreased $478,000, or 62%, to $291,000 for the thirteen weeks ended December 26, 2003, from $769,000 for the thirteen weeks ended December 27, 2002. Sales of GDX and related products during the prior period were higher due to the promotional efforts of our distributors during the launch of the product which began in July 2002 and a single program with a major pharmaceutical company in September 2002.

International revenue increased $24,000, or 1%, remaining approximately the same, $1.9 million for both the thirteen weeks ended December 26, 2002 and the thirteen weeks ended December 27, 2003. The increase in international revenue related primarily to the sale of our GDX and related products which increased $151,000, or 177%, primarily due to a single program in India, to $237,000 for the thirteen weeks ended December 26, 2003, from $86,000 for the thirteen weeks ended December 27, 2002. Revenue from the sale of single use test cassettes increased $90,000, or 8%, to $1.2 million for the thirteen weeks ended December 26, 2003 from $1.2 million for the thirteen weeks ended December 27, 2002. This was offset by LDX revenue which decreased by $219,000, or 49%, to $231,000 for the thirteen weeks ended December 26, 2003 from $450,000 for the thirteen weeks ended December 27, 2002. Sales of LDX products during the prior period were higher due to programs with two major pharmaceutical companies during the thirteen weeks ended December 27, 2002.

For the thirty-nine weeks ended December 26, 2003, revenue increased $5.3 million or 15%, to $40.4 million from $35.1 million for the thirty-nine weeks ended December 27, 2002. Sales of single use test cassettes increased $4.7 million, or 17%, from $28.0 million for the thirty-nine weeks ended December 27, 2002 to $32.8 million for the thirty-nine weeks ended December 26, 2003. Revenue for our LDX analyzer decreased $127,000, or 4%, to $2.9 million for the thirty-nine weeks ended December 26, 2003 from $3.0 million for the thirty-nine weeks ended December 27, 2002 due in part to an increase in promotional programs which involve placement of LDX analyzers at reduced prices or free of charge, contingent upon purchase commitments involving our single use test cassettes. Revenue for our GDX analyzer and related single use test cartridges increased $348,000, or 19%, to $2.2 million for the thirty-nine weeks ended December 26, 2003, from $1.8 million for the thirty-nine weeks ended December 27, 2002. Our GDX sales during the prior year period were primarily due to a single marketing program with one company and other product launch efforts from our distribution partners. Accessories sales increased $376,000, or 17%, to $2.6 million for the thirty-nine weeks ended December 26, 2003 from $2.2 million for the thirty-nine weeks ended December 27, 2002.

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For the thirty-nine weeks ended December 26, 2003, domestic revenue increased $4.4 million, or 15%, to $34.8 million from $30.4 million for the thirty-nine weeks ended December 27, 2002. The increase in revenue was attributable to the continued adoption by physicians of the ATP III guidelines for treatment of high cholesterol, the increased number of CLIA waived laboratories and increased growth in the use of statin drugs, all of which resulted in higher demand for our LDX and single use test cassettes. This resulted in a 29% revenue increase in the physician office laboratory market, which increased $5.1 million to $22.6 million during the thirty-nine weeks ended December 26, 2003, from $17.5 million for the thirty-nine weeks ended December 27, 2002. Most of the increase related to revenue from single use test cassettes, which increased 29%, while single use test cassettes unit volume increased 32% from the prior year period. Domestic revenue for our GDX analyzer and related single use test cartridges, which we began shipping in July 2002, decreased $34,000, or 2%, to $1.7 million for the thirty-nine weeks ended December 26, 2003, from $1.7 million for the thirty-nine weeks ended December 27, 2002.

International revenue increased $942,000, or 20%, to $5.6 million for the thirty-nine weeks ended December 26, 2003 from $4.7 million for the thirty-nine weeks ended December 27, 2002. The increase was primarily related to the continued impact of the launch by AstraZeneca PLC of its statin drug Crestor in the United Kingdom and Mexico, and the preparation for its launch in Germany, Spain and Italy. Most of the revenue increase resulted from the sale of single use test cassettes which increased $562,000, or 18%, to $3.8 million for the thirty-nine weeks ended December 26, 2003 from $3.2 million for the thirty-nine weeks ended December 27, 2002. Additionally, international revenue for our GDX and related products increased $383,000, or 319%, to $503,000 for the thirty-nine weeks ended December 26, 2003, from $120,000 for the thirty-nine weeks ended December 27, 2002. Our international GDX sales commenced in September 2002 and did not benefit from any single marketing program as did our domestic launch and continues to increase as a result of efforts from our distribution partners..

Cost of Goods Sold. Cost of goods sold includes direct labor, direct material, overhead and royalties. Cost of goods sold increased $597,000, or 11%, to $6.2 million for the thirteen weeks ended December 26, 2003 from $5.6 million for the thirteen weeks ended December 27, 2002. Most of the increase related to higher unit volume of products sold. Gross margins were 54% for both the thirteen weeks ended December 26, 2003 and December 27, 2002. Cassette production increased 45% while total factory spending increased $1.1 million or 31%, decreasing the average cost of products manufactured for the thirteen weeks ended December 26, 2003, compared to the thirteen weeks ended December 27, 2002. This was offset by an increase in promotional program expense tied directly to sales recognized during the thirteen weeks ended December 26, 2003. Factory spending increased due to increased scrap costs of $359,000, increased royalty expense of $207,000 and increases in wages and related costs of $319,000. As a part of the settlement agreement with Roche, we will pay what we believe is a reasonable ongoing royalty, that will be applied to only the HDL portion of cholesterol test cassettes sold by the Company. These payments, along with any future royalty payments, will be charged to cost of good sold as incurred.

For the thirty-nine weeks ended December 26, 2003, cost of goods sold increased $2.5 million, or 17%, to $17.3 million from $14.8 million for the thirty-nine weeks ended December 27, 2002. The increase in cost of goods sold primarily related to a 19% higher unit volume for single use test cassettes. Gross margins were 57% and 58% for the thirty-nine weeks ended December 26, 2003 and December 27, 2002, respectively. The decline in gross margin was due to a 2% decline in the average sale price of single use test cassettes and in part to an increase in promotional program expense tied directly to sales recognized during the thirty-nine weeks ended December 26, 2003. Cassette production increased 24% while total factory spending increased $1.7 million, or 17%, decreasing the average cost of products manufactured for the thirty-nine weeks ended December 26, 2003, compared to the thirty-nine weeks ended December 27, 2002. Factory spending increased due to increased scrap costs of $430,000, increased royalty expense of $294,000 and increases in wages and related costs of $406,000.

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Sales and Marketing Expenses. Sales and marketing expenses include salaries, commissions, bonuses, travel and expenses for outside services related to marketing programs. Sales and marketing expenses increased $526,000, or 18%, to $3.4 million for the thirteen weeks ended December 26, 2003 from $2.9 million for the thirteen weeks ended December 27, 2002. The increase was mainly attributable to higher spending for commissions as a result of sales promotions, and increased wages and related costs due to increased headcount. These increases were partially offset by a decrease in distributor program spending and advertising. As a percent of total revenue, sales and marketing expenses increased to 25% for the thirteen weeks ended December 26, 2003 from 24% for the thirteen weeks ended December 27, 2002. Over the balance of the fiscal year, we do not expect sales and marketing expenses to increase significantly as a percentage of total revenue.

For the thirty-nine weeks ended December 26, 2003, sales and marketing expenses increased $781,000, or 9%, to $9.5 million from $8.7 million for the thirty-nine weeks ended December 27, 2002. The increase in sales and marketing expenses was mainly attributable to an increase in wages and related costs including commission expenses of $762,000 and increased travel costs of $332,000. These increases were offset by lower advertising and trade show expenses of $376,000 during the thirty-nine weeks ended December 26, 2003. As a percent of total revenue, sales and marketing expenses decreased to 23% for the thirty-nine weeks ended December 26, 2003 from 25% for the thirty-nine weeks ended December 27, 2002.

Research and Development Expenses. Research and development expenses include salaries, bonuses, expenses for professional consulting services, supplies and depreciation of capital equipment. Research and development expenses increased $122,000, or 19%, to $754,000, for the thirteen weeks ended December 26, 2003 from $632,000 for the thirteen weeks ended December 27, 2002. The increase was mainly attributable to increases of $41,000 for wage and related costs, $40,000 for outside professional services and $31,000 in shared facilities expenses. All of these increases related to increased activities in new product development, including AST, High SensitivityCRP and DirectLDL. As a percent of total revenue, research and development expenses increased to 6% for the thirteen weeks ended December 26, 2003 from 5% for the thirteen weeks ended December 27, 2002. Over the balance of the fiscal year we do not expect research and development expenses to increase significantly as a percentage of total revenue.

For the thirty-nine weeks ended December 26, 2003, research and development expenses increased $475,000, or 25%, to $2.4 million from $1.9 million for the thirty-nine weeks ended December 27, 2002. The increase was mainly attributable to increases of $108,000 for material used in new product development, $125,000 for outside consultants and $120,000 for wages and related expenses. All of these increases related to accelerated efforts in new product development. As a percent of total revenue, research and development expenses increased to 6% for the thirty-nine weeks ended December 26, 2003 from 5% for the thirty-nine weeks ended December 27, 2002.

General and Administrative Expenses. General and administrative expenses include compensation, benefits and expenses for outside professional services, including information services, legal and accounting. General and administrative expenses increased $116,000 to $2.2 million for the thirteen weeks ended December 26, 2003 from $2.1 million for the thirteen weeks ended December 27, 2002. The increase related to $316,000 in higher fees for outside professional services and consulting, including legal and accounting due to costs resulting from increased regulatory requirements including the Sarbanes-Oxley Act of 2002 and a $232,000 increase in facilities and shared expenses.

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These increases were offset by a decrease of $582,000 in wages and related costs due to the recognition in the thirteen weeks ended December 27, 2002 of a $591,000 of restructuring expense in connection with the severance costs for two of the company s vice presidents and two additional employees, related, in part, to the divestiture of the WellCheck testing services business. As a percent of total revenue, general and administrative expenses decreased to 17% for the thirteen weeks ended December 26, 2003 from 18% for the thirteen weeks ended December 27, 2002. Legal expenses related to our settlement with Roche in connection with ongoing patent infringement litigation that were previously reported in general and administrative expenses are now reported as litigation and related expense

For the thirty-nine weeks ended December 26, 2003, general and administrative expenses increased $1.3 million, or 26%, to $6.4 million from $5.1 million for the thirty-nine weeks ended December 27, 2002. The increase related to $468,000 in higher fees for outside professional services and consulting, including legal and accounting, a $368,000 increase in directors and officers liability insurance premiums and a $232,000, and an increase in facilities and shared expenses. These increases were offset by a decrease of $588,000 in wages and related costs due to the recognition in the thirteen weeks ended December 27, 2002 of a $591,000 of restructuring expense in connection with the severance costs for two of the company s vice presidents and two additional employees, related, in part, to the divestiture of the WellCheck testing services business. As a percent of total revenue, general and administrative expenses increased to 16% for the thirty-nine weeks ended December 26, 2003 from 15% for the thirty-nine weeks ended December 27, 2002.

Other operating costs. For the thirty-nine weeks ended December 26, 2003, other operating costs were $250,000 with no corresponding costs for the thirteen weeks or thirty-nine weeks ended December 27, 2002. These costs related to the write-off of an option to purchase a patent, which we determined no longer had an economic value, during the thirteen weeks ended September 26, 2003.

Litigation and Other Related Expenses. For the thirteen weeks ended December 26, 2003, litigation and related expenses increased $7.3 million to $7.4 million. These costs related to our settlement with Roche in connection with ongoing patent infringement litigation. Pursuant to the settlement agreement, which serves as the basis for the dismissal of all patent litigation between us and Roche on a worldwide basis, we recognized a $7.0 million accrual due to Roche during the thirteen weeks ended December 26, 2003. As a part of this settlement, we will pay what we believe is a reasonable ongoing royalty that will be applied to only the HDL portion of cholesterol test cassettes we sell. These payments, along with any future royalty payments, will be charged to costs of good sold as they are incurred.

For the thirty-nine weeks ended December 26, 2003, litigation and related expenses increased $7.6 million to $7.8 million for the thirty-nine weeks ended December 27, 2003. These costs related to our settlement with Roche in connection with ongoing patent infringement litigation.

Interest and other income, net. Interest and other income, net, reflects income from the investment of cash balances and marketable securities, less the fees charged by financial institutions. Interest income decreased $35,000, or 36%, to $62,000 for the thirteen weeks ended December 26, 2003 from $97,000 for the thirteen weeks ended December 27, 2002. The decrease was primarily attributable to lower yields on securities investments. We expect income from securities investments will continue at the current rate unless there is an increase on the market yield on corporate bonds.

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For the thirty-nine weeks ended December 26, 2003, interest and other income decreased $43,000, or 14%, to $271,000 from $314,000 for the thirty-nine weeks ended December 27, 2002. The decrease related to lower yields on securities investments.

Income Taxes. For the thirteen weeks ended December 26, 2003, we recognized an income tax benefit of $2.5 million, compared to an income tax expense of $32,000 for the thirteen weeks ended December 27, 2002. The net tax benefit of $2.5 million includes a tax benefit of $2.9 million relating to the Roche settlement agreement and a tax provision of $343,000 on operating income from continuing operations, before the impact of the Roche settlement agreement.

For the thirty-nine weeks ended December 26, 2003, the we recognized an income tax benefit of $1.1 million, compared to an income tax expense of $187,000 for the thirty-nine weeks ended December 27, 2002. The net tax benefit of $1.1 million includes a tax benefit of $2.9 million relating to the Roche settlement agreement and a tax provision of $1.8 million on operating income from continuing operations, before the impact of the Roche settlement agreement.

Loss from sale of discontinued operations. Loss from sale of discontinued operations for the thirteen and thirty-nine weeks ended December 27, 2002 resulted from a $4.3 million write-off relating to the sale of WellCheck.

Discontinued Operations. Discontinued operations include all revenue, cost of goods sold, compensation, benefits, travel and expenses for outside professional services, including information services and legal consulting, related to the operations of the WellCheck business, which we sold on December 23, 2002. The net gain on discontinued operations of $8,000 for the thirteen weeks ended December 26, 2003 was primarily attributable to royalties related to TEAMS software, compared to the net loss from discontinued operations of $252,000 for the thirteen weeks ended December 27, 2002, which related to a loss from WellCheck operations for the thirteen weeks ended December 27, 2002.

For the thirty-nine weeks ended December 26, 2003, the net gain on discontinued operations was $47,000, compared to a net loss of $1.5 million for the thirty-nine weeks ended December 27, 2002. The net gain relates to royalty revenue for utilization of TEAMS software and adjustments to the previously recognized loss. The net loss from discontinued operations of $1.5 million for the thirty-nine weeks ended December 27, 2002 related to a loss from WellCheck operations for the thirty-nine weeks ended December 27, 2002.

Future contingent sales proceeds, including TEAMS royalties and payments contingent on the attainment of certain performance measures, will be recognized as earned as a component of discontinued operations.

Liquidity and Capital Resources

We have financed our operations primarily through the sale of equity securities and positive cash flow from operations. From our inception to December 26, 2003, we have raised $83.7 million in net proceeds from equity financings. As of December 26, 2003, we had $31.2 million of cash, cash equivalents and short and long-term marketable securities. In addition to these amounts, we have available a $4.0 million revolving bank line of credit with Wells Fargo Bank, N.A. While the line of credit is in effect, we are required to deposit assets with a collective value, as defined in the line of credit agreement, equivalent to no less than 100% of the outstanding principal balance. Amounts outstanding under the line of credit bear interest at either our choice of 0.5% below the bank s prime rate or 1.75% above the LIBOR rate, depending on the payment schedule. The line of credit agreement expires on

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September 1, 2004. As of December 26, 2003, we had no borrowings outstanding under this line of credit.

Cash, cash equivalents and total investments were $31.2 million at December 26, 2003, an increase of $5.1 million, or 20%, from $26.1 million at March 28, 2003. Cash provided by operations during the thirty-nine weeks ended December 26, 2003 was $6.2 million, which was $1.4 million, or 29%, higher than the $4.8 million for the thirty-nine weeks ended December 27, 2002. The increase related mainly to higher income from continuing operations, before the impact of the Roche settlement agreement accrual. For the thirty-nine weeks ended December 26, 2003, accounts receivable increased $1.2 million due to an increase in sales during the period. Additionally, accounts payable and accrued expenses increased $6.9 million primarily due to the Roche settlement agreement accrual, and accrued payroll and benefits increased $608,000.

Subsequent to the end of the quarter, on December 30, 2003, we made a payment to Roche of $7 million pursuant to the litigation settlement agreement.

Additions to plant and equipment totaled $2.7 million and $2.2 million for the first thirty-nine weeks ended December 26, 2003 and December 27, 2002, respectively. Capital spending for both the current and prior year was related to tenant improvements, expansion of our manufacturing capacity, and development and expansion of our information technology systems. We anticipate spending approximately $400,000 on additional capital expenditures for production equipment and other long lived assets for the balance of our current fiscal year.

Sales of common stock through the employee stock option program and employee stock purchase program were $1.5 million for the thirty-nine weeks ended December 26, 2003, which represented a decrease of $1.2 million, or 44%, from $2.7 million for the thirty-nine weeks ended December 27, 2002. The decline related to decreased exercises of stock options due to a decrease in the value of shares of our common stock on the open market.

Based on current plans and business conditions, we believe that our existing cash, cash equivalents, marketable securities, cash flow anticipated to be generated by future operations and available bank borrowings under our existing line of credit will be sufficient to meet our anticipated operating requirements for at least the next twelve months, including the Roche settlement agreement payment and future royalty payments to Roche as part of the settlement agreement. However, we cannot be certain that our underlying assumed levels of revenue and expenses will be accurate. We may be required to expend greater than anticipated funds if unforeseen difficulties arise relating to modifying or expanding facilities, obtaining necessary product regulatory approvals, scaling up manufacturing for new tests, arbitrating disputes or other matters.

Our future liquidity and capital requirements will depend upon numerous additional factors, including the cost and timing of expanding our manufacturing capacity, the number and type of new tests we may seek to develop, the success of these development efforts, the cost and timing of acquiring new products or technologies, the cost and timing of expansion of sales and marketing activities, the extent to which our existing and new products gain market acceptance, competing technological and market developments, the progress of commercialization efforts of our distributors, the cost involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights, developments related to regulatory and third-party reimbursement matters, a significant shortfall in operating results and other factors.

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In the event that additional financing is needed, we may seek to raise additional funds through debt, public or private financing, or collaborative relationships or arrangements. However, we may not be successful in obtaining necessary funds. Even if we do raise funds, any additional equity financing may be dilutive to our shareholders, and debt financing may involve restrictive covenants that limit the manner in which we operate. Collaborative arrangements, if necessary to raise additional funds, may require us to relinquish our rights to certain products or marketing territories. Our failure to raise capital on acceptable terms when needed could have a material adverse effect on our business, financial condition and results of operations. See Factors Affecting Future Operating Results.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of financial statements requires management to make estimates and judgments that affect the reported amounts of assets and liabilities, revenue and expenses and disclosures at the date of the financial statements. On an ongoing basis, we evaluate our estimates, including those related to accounts receivable, inventories and income taxes. We use authoritative pronouncements, historical experience and other assumptions as the basis for making estimates. Actual results could differ from these estimates.

We have made no changes to our critical accounting policies from those described in our most recent Annual Report on Form 10-K. For a description of critical accounting policies, please refer to the Annual Report on Form 10-K for the fiscal year ended March 28, 2003.

Recent Accounting Pronouncements

In May 2003, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 150, *Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity*. SFAS No. 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. This standard is effective for financial instruments entered into or modified after May 31, 2003. We adopted this standard and the adoption of this standard had no material impact on our financial statements.

In April 2003, the FASB issued SFAS No. 149, *Amendment of Statement 133 of Derivative Instruments and Hedging Activities.* SFAS No. 149 amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts. This standard is effective for contracts entered into or modified after June 30, 2003. We adopted this standard and the adoption of this standard had no material impact on our financial statements.

Factors Affecting Future Operating Results

We have a history of operating losses and fluctuating operating results, which may result in the market price of our common stock declining

Our revenue and operating results have varied significantly from quarter to quarter in the past and may continue to fluctuate in the future. As of December 26, 2003, we had an accumulated deficit of $39.3 million. Our first profitable quarter was the third quarter of fiscal 1998, and our first profitable

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year was fiscal 1998. We recorded a net loss of $2.6 million for fiscal 2001, a net profit of $5.6 million for fiscal 2002 and a net profit of $4.9 million for fiscal 2003. The following are some of the factors that could cause our revenue, operating results and margins to fluctuate significantly from quarter to quarter:

- the timing and level of market acceptance of the LDX System and the GDX System;
- variations in manufacturing efficiencies;
- the timing of the introduction, availability and market acceptance of new tests and products;
- the timing and level of expenditures associated with research and development activities;
- the timing and establishment of strategic distribution arrangements and the success of the activities conducted under such arrangements;
- changes in demand for our products based on changes in third-party reimbursement, competition, changes in government regulation and other factors;
- the timing of significant orders from, and shipments to, customers;
- product pricing and discounts;
- additional cost of expanded leased facilities;
- promotional program spending by both domestic and European pharmaceutical companies;
- variations in the mix of products sold; and
- general economic conditions.

These and other factors are difficult to predict and could have a material adverse effect on our business, financial condition and operating results. Fluctuations in quarterly demand for our products may cause our manufacturing operations to fluctuate in volume, increase uncertainty in operational planning and/or affect cash flows from operations. We commit to many of our expenses in advance, based on our expectations of future business needs. These costs are largely fixed in the short-term. As a result, when business levels do not meet expectations, our fixed costs will not be recovered and we will experience losses. This situation is likely to result in the future because of the variability and unpredictability of our revenue. This also means that our results will likely not meet the expectations of public market security analysts or investors at one time or another, which may result in the market price of our common stock declining.

Our business depends on our ability to protect our proprietary technology through patents and other means and to operate without infringing the proprietary rights of others

Our success depends in part on our ability to develop and maintain the proprietary aspects of our technology and operate without infringing the proprietary rights of others. We have nine United States patents, one German patent and have filed patent applications relating to our technology internationally under the Patent Cooperation Treaty and individual foreign patent applications. The risks of relying on the proprietary nature of our technology include:

- our pending patent applications may not result in the issuance of any patents, or, if issued, such patents may not offer protection against competitors with similar technology;
- our patents may be challenged, invalidated or circumvented in the future, and the rights created under our patents may not provide a competitive advantage;

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competitors, many of whom have substantially greater resources than us and have made substantial investments in competing technologies, may seek to apply for and obtain patents covering technologies that are more effective than ours. This could render our technologies or products obsolete or uncompetitive or could prevent, limit or interfere with our ability to make, use or sell our products either in the United States or in international markets;

the medical products industry has been characterized by extensive litigation regarding patents and other intellectual property rights; and

an adverse determination in litigation or interference proceedings to which we may become a party could subject us to significant liabilities to third parties or require us to seek licenses from third parties, which may not be available on commercially reasonable terms or at all.

We may in the future become subject to patent infringement claims and litigation or interference proceedings conducted in the United States Patent and Trademark Office to determine the priority of inventions. Litigation may also be necessary to enforce any patents issued to us, to protect our trade secrets or know-how or to determine the enforceability, scope and validity of the proprietary rights of others. The defense and prosecution of intellectual property suits, patent interference proceedings and related legal and administrative proceedings are both costly and time consuming and will likely result in substantially diverting the attention of technical and management personnel from our business operations. We may also be subject to significant damages or equitable remedies regarding the development and sale of our products and operation of our business.

For example, on December 19, 2003, we entered into a settlement agreement and license agreement with Roche, which settled all existing patent litigation between the parties on a worldwide basis. The settlement included a lump sum payment by us to Roche in the amount of $7 million (which was paid on December 30, 2003) and the dismissal of all patent claims between the parties. As a part of the settlement, we will pay Roche an ongoing royalty and Roche will grant an irrevocable, non-exclusive, worldwide license to us for its patents related to HDL cholesterol. In addition, the parties have also agreed upon a mechanism for the resolution of future patent infringement disputes. We believe that any such dispute resolution will confirm that our HDL cholesterol test cassette, currently under development, does not infringe Roche s patents. If however, upon the resolution of any such dispute, it is ultimately determined that our new HDL cholesterol test cassette is covered by Roche s patents, we will pay Roche the same ongoing royalty.

We rely on trade secrets, technical know-how and continuing invention to develop and maintain our competitive position. Others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technology. We may also be unable to adequately protect our right to our trade secrets.

We depend on technology that we license from others, which may not be available to us in the future and would prevent us from introducing new products and harm our business

Our current products incorporate technologies that are the subject of patents issued to, and patent applications filed by, others. We have obtained licenses for certain of these technologies. We may in the future be required to obtain licenses for new products. We may be unable to obtain licenses for technology patented by others on commercially reasonable terms, or at all. We also may be unable to develop alternative approaches if we are unable to obtain licenses. Our future licenses may also not be adequate for the operation of our business. Failure to obtain adequate licenses on commercially reasonable terms could prevent us from introducing our products and severely harm our business.

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Our stock price is likely to continue to be volatile, which could result in substantial losses for investors

The market price of our common stock has in the past been, and in the future is likely to be, highly volatile. These fluctuations could result in substantial losses for investors. Our stock price may fluctuate for a number of reasons including:

- quarterly variations in our operating results;
- developments in or disputes regarding patent or other proprietary rights;
- announcements of technological or competitive developments by us and our competitors;
- regulatory developments regarding us or our competitors;
- changes in the current structure of the healthcare financing and payment systems;
- stock market price and volume fluctuations, which have particularly affected the market prices for medical products and high technology companies and which are often been unrelated to the operating performance of such companies; and
- general economic, political and market conditions.

With the advent of the internet, new avenues have been created for the dissemination of information. We do not have control over the information that is distributed and discussed on electronic bulletin boards and investment chat rooms. The motives of the people or organizations that distribute such information may not be in our best interest or in the interest of our shareholders. This, in addition to other forms of investment information, including newsletters and research publications, could result in a significant decline in the market price of our common stock.

In addition, stock markets have from time to time experienced extreme price and volume fluctuations. The market prices for diagnostic product companies have been affected by these market fluctuations and such effects have often been unrelated to the operating performance of such companies. These broad market fluctuations may cause a decline in the market price of our common stock.

Securities class action litigation is often brought against a company after a period of volatility in the market price of its stock. This type of litigation has been brought against us in the past and could be brought against us in the future, which could result in substantial expense and damage awards and divert management s attention from running our business.

If third-party reimbursement for use of our products is eliminated or reduced, our sales will be greatly reduced and our business may fail

In the United States, healthcare providers that purchase products such as the LDX System and the GDX System generally rely on their patients healthcare insurers, including private health insurance plans, federal Medicare, state Medicaid and managed care organizations, to reimburse all or part of the cost of the procedure in which the product is being used. We will be unable to successfully market our products if their purchase and use is not subject to reimbursement from government health authorities, private health insurers and other third-party payors. If this reimbursement is not available or is limited, healthcare providers will be much less likely to use our products, our sales will be greatly reduced and our business may fail.

There are current conditions in the healthcare industry that increase the possibility that third-party payors may reduce or eliminate reimbursement for tests using our products in certain settings. These conditions include:

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third-party payors are increasingly scrutinizing and challenging the prices charged for medical products and services;

healthcare providers are moving toward a system in which employers are requiring participants to bear a greater burden of the cost of their healthcare benefits which could result in fewer elective procedures, such as the use of our products for diagnostic screening;

general uncertainty regarding what changes will be made in the reimbursement methods used by third-party payors and how that will affect the use of products such as ours, which may deter healthcare providers from adopting the use of our products; and

an overall escalating cost of medical products and services has led to and will continue to lead to increased pressures on the healthcare industry, both domestic and international, to reduce the cost of products and services, including products offered by us.

Market acceptance of our products in international markets is also dependent, in part, on the availability of reimbursement or funding, as the case may be, within prevailing healthcare systems. Reimbursement, funding and healthcare payment systems in international markets vary significantly by country and include both government sponsored healthcare and private insurance. Third-party reimbursement and coverage may not be available or adequate in either the United States or international markets, and current reimbursement or funding amounts may be decreased in the future. Also, future legislation, regulation or reimbursement policies of third-party payors may adversely affect demand for our products or our ability to sell our products on a profitable basis. Any of these events could materially harm our business.

We may be unable to effectively compete against other providers of diagnostic products, which could cause our sales to decline

The market for diagnostic products in which we operate is intensely competitive. Our business is based on the sale of diagnostic products that physicians and other healthcare providers can administer in their own facilities without sending samples to laboratories. Thus, our competition consists primarily of clinical reference laboratories and hospital-based laboratories, as well as manufacturers of bench top analyzers. To achieve and maintain market acceptance for the LDX System and the GDX System, we must demonstrate that the LDX System and the GDX System are attractive alternatives to bench top analyzers as well as to clinical and hospital laboratories. Even if we can demonstrate that our products are more cost effective and save time, physicians and other healthcare providers may resist changing their established source of such tests. The LDX System and the GDX System may be unable to compete with these other testing services and analyzers. In addition, companies with a significant presence in the market for clinical diagnostics, such as Abbott Laboratories, Bayer Diagnostics, Beckman Coulter, Inc. and Roche Diagnostics (a subsidiary of Roche Holdings, Ltd.) have developed or are developing analyzers designed for point of care testing. These competitors have substantially greater financial, technical, research and other resources and larger, more established marketing, sales, distribution and service organizations than us. These competitors also offer broader product lines than us, have greater name recognition than us and offer discounts as a competitive tactic. In addition, several smaller companies are currently making or developing products that compete or will compete with ours. We may not have the financial resources, technical expertise or marketing, distribution or support capabilities to compete successfully in the future. Even if we do have such resources and capabilities, we may not employ them successfully.

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Our LDX System and GDX System have not yet achieved broad market acceptance in all of our target markets and if broad market acceptance does not occur, our operating results will be harmed

Our LDX System, including the LDX Analyzer and single use test cassettes, currently accounts for substantially all of the revenue of our business. If this revenue does not grow, our overall business will be severely harmed. In addition, we have limited experience marketing and distributing the GDX System, and it is uncertain whether this product will achieve broad market acceptance in our target markets and generate significant revenue in the future. For us to increase revenue, sustain profitability and maintain positive cash flows from operations, the LDX System and the GDX System must continue to and begin to gain market acceptance among healthcare providers, particularly physician office laboratories. We have made only limited sales of the LDX System to physician office laboratories to date relative to the size of the available market. Factors that could prevent broad market acceptance of the LDX System and the GDX System include:

low levels of awareness of the availability of our technology in both the physician and other customer groups;

the availability and pricing of other testing alternatives;

many managed care organizations have contracts with laboratories, which require participating or employed physicians to send patient specimens to contracted laboratories;

physicians are under growing pressure by Medicare and other third-party payors to limit their testing to medically necessary tests; and

a decrease in the amount of reimbursement for performing tests on the LDX System and the GDX System.

If our LDX System does not achieve broader market acceptance and our GDX System does not achieve favorable market acceptance, our business will not grow. Even if we are successful in continuing to place our LDX Analyzer at physician office laboratories and other near-patient testing sites and marketing our GDX System, there can be no assurance that placement of these products will result in sustained demand for our single use test cassettes and single use test cartridges.

In addition, we must leverage our installed base of systems in order to increase the sales of our single use test cassettes and single use test cartridges. If we are unable to increase the usage of cassettes on our current installed base, we will have to identify new customers and induce them to purchase an analyzer, which requires more time and effort and has a significantly larger purchase price than the single use test cassettes.

As a result of these many hurdles to achieving broad market acceptance for the LDX System and the GDX System, demand may not be sufficient to sustain revenue and profits from operations. Because the LDX System currently contributes the vast majority of our revenue, and we expect the GDX System to contribute a material portion of our revenue in the future, we could be required to cease operations if the LDX System and the GDX System do not achieve and maintain a significant level of market acceptance.

If we do not successfully develop, acquire or form alliances to introduce and market new tests and products, our future business will be harmed

We believe our business will not grow significantly if we do not develop, acquire or form alliances for new tests and products to use in conjunction with the LDX System and the GDX System. If we do not develop, market introduce new tests and products to the market, our business will not grow

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significantly and will be harmed. Developing new tests involves many significant problems and risks, including:

- research and development is a very expensive process;
- research and development takes a very long time to result in a marketable product;
- significant costs (including diversion of resources) may be incurred in development before knowing if the development will result in a test that is commercially viable;
- a new test will not be successful unless it is effectively marketed to its target market;
- the manufacturing process for a new test must be reliable, cost efficient and high volume and must be developed and implemented in a timely manner to produce the test for sale;
- new tests must meet a significant market need to be successful; and
- new tests must obtain proper regulatory approvals to be marketed.

We could experience difficulties that delay or prevent the successful development, introduction and marketing of new tests and products. For example, regulatory clearance or approval of any new tests or products may not be granted on a timely basis, or at all. We have experienced difficulties obtaining regulatory approval for tests in the past. Because the evaluation of applications by the FDA for CLIA waived status is not based on precisely defined, objectively measurable criteria, we cannot predict the likelihood of obtaining CLIA waived status for future products.

We face risks from failures in our manufacturing processes

We manufacture all of the single use test cassettes that are used with the LDX Analyzer. The manufacture of single use test cassettes is a highly complex and precise process that is sensitive to a wide variety of factors. Significant additional resources, implementation of additional manufacturing equipment or changes in our manufacturing processes have been, and may continue to be, required for the scaling-up of each new product prior to commercialization or in order to meet increasing customer demand once commercialization begins, and this work may not be completed successfully or efficiently. In the past, we have experienced lower than expected manufacturing yields that have adversely affected gross margins and delayed product shipments. If we do not maintain acceptable manufacturing yields of test cassettes or experience product shipment delays, our business, financial condition and operating results could be materially adversely affected. We may reject or be unable to sell a substantial percentage of test cassettes because of:

- raw materials variations or impurities;
- manufacturing process variances and impurities; and
- decreased manufacturing equipment performance.

Our LDX and cassette manufacturing lines would be costly and time consuming to repair or replace if their operation were interrupted. The interruption of our manufacturing operations or the loss of associates dedicated to the manufacturing facility could severely harm our business. The risks involving our manufacturing lines include:

- as our production levels have increased, we have been required to use our machinery more hours per day and the down time resulting from equipment failure has increased;
- the custom nature of much of our manufacturing equipment increases the time required to remedy equipment failures and replace equipment;

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we have a limited number of associates dedicated to the operation and maintenance of our manufacturing equipment, the loss of whom could impact our ability to effectively operate and service such equipment;

we manufacture all of our cassettes at our Hayward, California manufacturing facility, so manufacturing operations are at risk to interruption from earthquake, fire, power outages or other events affecting this one location; and

we have recently completed the process of scaling up a new manufacturing line to production capability. Our failure to maintain production levels and operate this line at production capability for an extended period would impact our ability to increase our manufacturing capacity.

Our operating results may suffer if we do not reduce our manufacturing costs

We believe we will be required to reduce manufacturing costs for new and existing test cassettes to achieve sustained profitability. We currently operate two manufacturing lines for dry chemistry cassettes. A third manufacturing line is currently used primarily for research and development purposes. The complexity and custom nature of our manufacturing process increases the amount of time and money required to add an additional manufacturing line. In addition, we may need to implement additional cassette manufacturing cost reduction programs. Failure to maintain full production levels for our new manufacturing line could prevent us from satisfying customer orders in a timely manner, which could lead to customer dissatisfaction and loss of business and a failure to reduce manufacturing costs for dry chemistry tests, which could prevent us from achieving sustained profitability.

Our future results could be harmed by economic, political, regulatory and other risks associated with international sales

Historically, a significant portion of our total revenue has been generated outside of the United States. International revenue as a percentage of our total revenue was approximately 14% in fiscal 2003 and 19% in fiscal 2002. We anticipate that international revenue will continue to represent a significant portion of our total revenue in the future. Our revenue is generally denominated in United States dollars; however, a strengthening of the dollar could make our products less competitive in foreign markets and, as a result, our future revenue from international operations may be unpredictable. We make foreign currency denominated purchases related to our GDX System in the United Kingdom. This exposes us to risks associated with currency exchange fluctuations. To minimize this risk, we have undertaken certain foreign currency hedging transactions; however, weakening of the dollar could make the cost of the GDX System less competitive in the domestic market, resulting in less predictable domestic revenue.

In addition to foreign currency risks, our international sales and operations may also be subject to the following risks:

our dependency on pharmaceutical companies promotional programs as a primary source of international revenue;

unexpected changes in regulatory requirements;

the impact of recessions in economies outside the United States;

changes in a specific country s or region s political or economic conditions, particularly in emerging nations;

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less effective protection of intellectual property rights in some countries;

changes in tariffs and other trade protection measures;

difficulties in managing international operations; and

potential insolvency of international distributors and difficulty in collecting accounts receivable and longer collection periods.

If we are unable to minimize the foregoing risks, they may harm our current and future international sales and, consequently, our business.

We depend on single source suppliers for certain materials used in our manufacturing process and failure of our suppliers to provide materials to us could harm our business

We currently depend on single source vendors to provide certain subassemblies, components and raw materials used in the manufacture of our products. We also depend on a third-party manufacturer for the GDX System. Any supply interruption in a single sourced material or product could restrict our ability to manufacture and distribute products until a new source of supply is identified and qualified. We may not be successful in qualifying additional sources of supply on a timely basis, or at all. Failure to obtain a usable alternative source or product could prevent us from manufacturing and distributing our products, resulting in inability to fill orders, customer dissatisfaction and loss of business. This would likely severely harm our business. In addition, an uncorrected impurity or supplier s variation in material, either unknown to us or incompatible with our manufacturing process, could interfere with our ability to manufacture and distribute products. Because we are a small customer of many of our suppliers and we purchase their subassemblies, components and materials with purchase orders instead of long-term commitments, our suppliers may not devote adequate resources to supplying our needs. Any interruption or reduction in the future supply of any materials currently obtained from single or limited sources could severely harm our business.

We depend on distributors to sell our products and failure to successfully maintain these relationships could adversely affect our ability to generate revenue

To increase revenue and achieve sustained profitability, we will have to successfully maintain our existing distribution relationships and develop new distribution relationships. We depend on our distributors to assist us in promoting market acceptance of the LDX System and the GDX System. However, we may be unable to enter into and maintain new arrangements on a timely basis, or at all. Even if we do enter into additional distributor relationships, those distributors may not devote the resources necessary to provide effective sales and marketing support to our products. In addition, our distributors sell products offered by our competitors. If our competitors offer our distributors more favorable terms or have more products available to meet their needs or utilize the leverage of broader product lines sold through the distributor, those distributors may de-emphasize or decline to carry our products. In addition, our distributors order decision-making process is complex and involves several factors, including end-user demand, warehouse allocation and marketing resources, which can make it difficult to accurately predict total sales for the quarter until late in the quarter. In order to keep our products included in distributors marketing programs, in the past we have provided promotional goods or made short-term pricing concessions. Our distributors could also modify their business practices, such as payment terms, inventory levels or order patterns. If we are unable to maintain successful relationships with distributors or expand our distribution channels or we experience unexpected changes in payment terms, inventory levels or other practices by our distributors, our business will suffer.

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We rely on a limited number of customers for a substantial part of our revenue

Sales to a limited number of customers have accounted for a significant portion of our revenue in each fiscal period. We expect that sales to a limited number of customers will continue to account for a substantial portion of our total revenue in future periods. Our top ten customers comprised 63% of our revenue in fiscal 2003. In fiscal 2003, Physicians Sales and Service (PSS) accounted for approximately 22% of our total revenue and McKesson Medical Surgical (McKesson) accounted for 9% of our total revenue. In fiscal 2002, PSS accounted for approximately 20% of our total revenue. We have experienced periods in which sales to some of our major customers, as a percentage of total revenue, have fluctuated due to delays or failures to place expected orders. We do not have long-term agreements with any of our customers, who generally purchase our products pursuant to cancelable short-term purchase orders. If we were to lose a major customer or if orders by or shipments to a major customer were to otherwise decrease or be delayed, our operating results would be harmed.

Recently enacted and proposed changes in securities laws and regulations will increase our costs.

The Sarbanes-Oxley Act of 2002 along with other recent and proposed rules from the Securities and Exchange Commission and Nasdaq require changes in our corporate governance, public disclosure and compliance practices. Many of these new requirements will increase our legal and financial compliance costs, and make some corporate actions more difficult, such as proposing new or amendments to stock option plans, which now require shareholder approval. These developments could make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These developments also could make it more difficult for us to attract and retain qualified executive officers and qualified members of our board of directors, particularly to serve on our audit committee.

Our products are subject to multiple levels of government regulation and any regulatory changes are difficult to predict and may be damaging to our business

The manufacture and sale of our diagnostic products, including the LDX System and the GDX System, is subject to extensive regulation by numerous governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies. We are unable to commence marketing or commercial sales in the United States of any of the new tests we develop until we receive the required clearances and approvals. The process of obtaining required regulatory clearances and approvals is lengthy, expensive and uncertain. As a result, our new tests under development, even if successfully developed, may never obtain such clearance or approval. Additionally, certain material changes to products that have already been cleared or approved are subject to further review and clearance or approval. Medical devices are subject to continual review, and later discovery of previously unknown problems with a cleared product may result in restrictions on the product s marketing or withdrawal of the product from the market. If we lose previously obtained clearances, or fail to comply with existing or future regulatory requirements, we may be unable to market the affected products, which would depress our revenue and severely harm our business.

In addition, any future amendment or addition to regulations impacting our products could prevent us from marketing the LDX System and the GDX System. Regulatory changes could hurt our business by increasing burdens on our products or by reducing or eliminating certain competitive advantages of the LDX System s and the GDX System s waived status. Food and Drug Administration clearance or approval of products such as ours can be obtained by either of two processes:

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the 510(k) clearance process, which generally takes from four to 12 months but may take longer; and

the pre-market approval process, which is a longer and more costly process than a 510(k) clearance process, involves the submission of extensive supporting data and clinical information and generally takes one to three years but may take significantly longer.

If our future products are required to obtain a pre-market approval, this would significantly delay our ability to market those tests and significantly increase the costs of development.

The use of our products and those of our competitors is also affected by federal and state regulations, which provide for regulation of laboratory testing, as well as by the laws and regulations of foreign countries. The scope of these regulations includes quality control, proficiency testing, personnel standards and inspections. In the United States, clinical laboratory testing is regulated under the Clinical Laboratory Improvement Act of 1976.

The LDX Analyzer, our total cholesterol, high density lipoproteins, triglycerides and glucose tests in any combination, our ALT test cassette, the GDX Analyzer and A1C test cartridges have been classified as waived from the application of many of the requirements under the CLIA. We believe this waived classification is critical for our products to be successful in their domestic markets. Any failure of our new tests to obtain waived status under the CLIA will severely limit our ability to commercialize such tests. Loss of waived status for existing diagnostic products or failure to obtain waived status for new products could limit our revenue from sales of such products, which would severely harm our business.

We may not be able to use some or all of our deferred tax asset, which may adversely affect our financial results.

During fiscal 2003 we determined, based on eight consecutive quarters of income from continuing operations, it would be prudent to reduce our tax valuation allowance by $4.2 million reflecting the economic benefits of our enterprise. Changes in existing tax law or adoption of new governmental tax laws or policies could limit, prevent or delay the use of our tax asset. Additionally, changes in the general domestic or world economic condition could result in significant reduction, or elimination of taxable income precluding us from using or eliminating our deferred tax asset.

In addition, United States income tax law imposes limitations on the ability of corporations to use net operating loss carryforwards if the corporation experiences a more than 50% change in ownership during any three-year period. We cannot assure you that we will not take actions, such as the issuance of additional stock, that would cause an ownership change to occur. Accordingly, we may be limited to the amount we can use in any given year, so even if we have substantial net income, we may not be able to use our net operating loss carryforwards before they expire. In addition, the net operating loss carryforwards are subject to examination by the Internal Revenue Service, or IRS, and are thus subject to adjustment or disallowance resulting from any such IRS examination.

If we have taxable income in the future, and we are unable to fully utilize our net operating loss carryforwards, our future tax payments could be higher and our financial results may suffer.

We may face fines or our manufacturing facilities could be closed if we fail to comply with manufacturing and environmental regulations

Our manufacturing processes and, in certain instances, those of our contract manufacturers, are subject to stringent federal, state and local regulations governing the use, generation, manufacture, storage, handling and disposal of certain materials and wastes. Failure to comply with present or future regulations could result in many things, including warning letters, fines, injunctions, civil penalties,

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recall or seizure of products, total or partial suspension of production, refusal of the government to grant pre-market clearance or pre-market approval for devices, withdrawal of approvals and criminal prosecution. Any of these developments could harm our business. We and our contract manufacturers are also subject to federal, state and foreign regulations regarding the manufacture of healthcare products and diagnostic devices, including:

- Quality System Regulations, which requires manufacturers to be in compliance with Food and Drug Administration regulations;
- ISO9001/EN46001 requirements, which is an industry standard for maintaining and assuring conformance to quality standards; and
- other foreign regulations and state and local health, safety and environmental regulations, which include testing, control and documentation requirements.

Changes in existing regulations or adoption of new governmental regulations or policies could prevent or delay regulatory approval of our products or require us to incur significant costs to comply with manufacturing and environmental regulations, which could harm our business.

A general economic downturn in the United States or abroad may reduce our revenue and harm our business

The primary customers for our products are physician office laboratories and entities conducting health promotion programs. Any significant downturn in domestic or global economic conditions which results in the reduction of the capital spending budgets of our customers or a delay in capital equipment purchases would likely result in a decline in demand for our products and could be detrimental to our business. Economic growth in the United States and other countries has slowed significantly and many commentators believe that the United States economy is experiencing a recession. Overall, customer spending decisions are being more closely scrutinized. These conditions have negatively impacted our business and may continue to do so if they persist.

We may pursue strategic acquisitions which could have an adverse impact on our business if they are unsuccessful

We continue to evaluate strategic opportunities available to us and we may pursue product, technology or business acquisitions. These acquisitions could be very costly, could result in dilution to existing investors and could result in integration problems that harm our business as a whole. Any acquisition could result in expending significant amounts of cash, issuing potentially dilutive equity securities or incurring debt or unknown liabilities associated with the acquired business. In addition, our acquisitions may not be successful in achieving our desired strategic objectives, which could materially harm our operating results and business. Acquisitions may also result in difficulties in assimilating the operations, technologies, products, services and personnel of the acquired company or business or in achieving the cost savings or other financial benefits we anticipated. These difficulties could result in additional expenses, diversion of management attention and an inability to respond quickly to market issues. Any of these results could harm us financially.

If we are successful in growing sales, our business will be harmed if we cannot effectively manage the operational and management challenges of growth

If we are successful in achieving and maintaining market acceptance for the LDX System and the GDX System, we will be required to expand our operations, particularly in the areas of sales, marketing and manufacturing. As we expand our operations, this expansion will likely result in new and increased

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responsibilities for management personnel and place significant strain on our management, operating and financial systems and resources. To accommodate any such growth and compete effectively, we will be required to implement and improve our information systems, procedures and controls, and to expand, train, motivate and manage our work force. Our personnel, systems, procedures and controls may not be adequate to support our future operations. Any failure to implement and improve operational, financial and management systems or to manage our work force as required by future growth, if any, could harm our business and prevent us from improving our financial condition as a result of increased sales.

We depend upon key employees in a competitive market for skilled personnel, and, without additional qualified associates, we cannot grow our business

Our success depends in significant part on the continued service of certain key scientific, technical, regulatory and managerial personnel. Our success will also require us to continue to identify, attract, hire and retain additional highly qualified personnel in those areas. Competition for qualified personnel in our industry is very competitive due to the limited number of people available with the necessary technical skills and understanding of our industry. We may be unable to retain our key personnel or attract or retain other necessary highly qualified personnel in the future, which would harm the development of our business.

Product liability and professional liability suits against us could result in expensive and time consuming litigation, payment of substantial damages and an increase in our insurance rates

Sale and use of our products and the past performance of testing services by our formerly wholly owned subsidiary could lead to the filing of a product liability or professional liability claim. If any of these claims are brought, we may have to expend significant resources defending against them. If we are found liable for any of these claims, we may have to pay damages that could severely hurt our financial position. Loss of these claims could also hurt our reputation, resulting in our losing business and market share. The medical testing industry has historically been litigious, and we face financial exposure to these liability claims if use of our products results in personal injury or improper diagnosis. We also face the possibility that defects in the design or manufacture of our products might necessitate a product recall.

We currently maintain product liability insurance and professional liability insurance for claims relating to the past performance of testing services, but there can be no assurance that the coverage limits of our insurance policies will be adequate. Insurance is expensive and difficult to obtain, and we may be unable to maintain product liability insurance in the future on acceptable terms or in sufficient amounts to protect us against losses due to product liability. Inability to maintain insurance at an acceptable cost or to otherwise protect against potential product liability could prevent or inhibit the continued commercialization of our products. In addition, a product liability or professional liability claim in excess of relevant insurance coverage or a product recall could severely harm our financial condition.

If the healthcare system in the United States undergoes fundamental change, these changes may harm our business

We believe that the healthcare industry in the United States is likely to undergo fundamental changes due to current political, economic and regulatory influences. We anticipate that Congress, state legislatures and the private sector will continue to review and assess alternative healthcare delivery and payment systems. Potential alternatives include mandated basic healthcare benefits, controls on

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healthcare spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, the creation of large insurance purchasing groups, price controls and other fundamental changes to the healthcare delivery system. We expect legislative debate to continue in the future and for market forces to demand reduced costs. We cannot predict what impact the adoption of any federal or state healthcare reform measures, future private sector reform or market forces may have on our business. Any changes in the healthcare system could potentially have extremely negative effects on our business.

We may need additional capital in the future to support our growth, and such additional funds may not be available to us

We intend to expend substantial funds for capital expenditures and working capital related to research and development, expansion of sales and marketing activities and other working capital and general corporate purposes. Although we believe our cash, cash equivalents, marketable securities, cash flow anticipated to be generated by future operations and available bank borrowings under an existing line of credit will be sufficient to meet our operating requirements for the foreseeable future, we may still require additional financing. For example, we may be required to expend greater than anticipated funds if unforeseen difficulties arise in expanding manufacturing capacity for existing cassettes or in the course of completing required additional development, obtaining necessary regulatory approvals, obtaining waived status under CLIA or introducing or scaling up manufacturing for new tests.

If we need additional capital in the future, we may seek to raise additional funds through public or private financing, collaborative relationships or other arrangements. Any additional equity financing may be dilutive to our existing shareholders or have rights, preferences and privileges senior to those of our existing shareholders. If we raise additional capital through borrowings, the terms of such borrowings may impose limitations on how our management may operate the business in the future. Collaborative arrangements, if necessary to raise additional funds, may require us to relinquish our rights to technologies, products or marketing territories. Our failure to raise capital on acceptable terms when needed could prevent us from developing our products and our business.

We have made use of a device to limit the possibility that we are acquired, which may mean that a transaction that shareholders are in favor of or are benefited by may be prevented

Our Board of Directors has the authority to issue up to 5,000,000 shares of preferred stock and to determine the rights, preferences, privileges and restrictions of such shares without any further vote or action by our shareholders. To date, our Board of Directors has designated 25,000 shares as Series A participating preferred stock in connection with our poison pill antitakeover plan. The issuance of preferred stock under certain circumstances could have the effect of delaying or preventing an acquisition of our company or otherwise adversely affecting the rights of the holders of our stock. The poison pill may have the effect of rendering more difficult or discouraging an acquisition of our company which is deemed undesirable by our board of directors. The poison pill may cause substantial dilution to a person or group attempting to acquire us on terms or in a manner not approved by our board of directors, except pursuant to an offer conditioned on the negation, purchase or redemption of the rights issued under the poison pill.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Quantitative Disclosures

Our exposure to market risks is inherent in our operations, primarily to interest rates relating to our investment portfolio.

We are subject to interest rate risks on cash and cash equivalents, available for sale marketable securities and any future financing requirements. Interest rate risks related to marketable securities are managed by managing maturities in our marketable securities portfolio.

We have concluded that the fair market value of our investment portfolio or related income would not be significantly impacted by short term changes in interest rates due to the nature of our marketable securities, which have maturity dates that do not exceed fiscal 2007 and have primarily fixed interest rates.

We enter into forward exchange contracts to manage foreign currency exposures arising from inventory purchases and accounts payable denominated in foreign currencies. Our policy is to hedge 100% of all committed purchase contracts and a lesser percentage for forecasted purchases. As of December 26, 2003, we had outstanding forward contracts to purchase £478,000 for approximately $750,000. The open contracts mature at various dates through May 17, 2004 and hedge certain forecasted inventory purchases denominated in the British Pound Sterling. The unrealized gain on the forward contracts as of December 26, 2003 was $96,000, all of which is expected to be reclassified to earnings within the next 12 months. There was no gain or loss recorded in the period from hedge ineffectiveness or from forecasted transactions no longer expected to occur. We do not enter into foreign exchange forward contracts for trading purposes. We do not expect gains or losses on these contracts to have a material impact on our financial results.

The following table presents the future principal cash flows or amount and related weighted average interest rates expected by year for our existing cash and cash equivalents, marketable securities and long-term investments.

	Fiscal Year					
	2004	2005	2006	2007	Total	Fair Value
	(in thousands)					
Cash, cash equivalents	$9,974	$	$	$	$ 9,974	$ 9,974
Short-term marketable securities	$1,412	$11,545	$	$	$12,957	$12,957
Weighted average interest rate	1.18%	3.86%			2.60%	
Long-term marketable securities	$	$ 1,998	$6,122	$ 106	$ 8,226	$ 8,226
Weighted average interest rate		3.59%	3.11%	4.36%	3.25%	

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Qualitative Disclosures

Our primary interest rate risk exposures relate to:

the available for sale securities will fall in value if market interest rates increase; and

the impact of interest rate movements on our ability to obtain adequate debt financing to fund future operations.

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

ITEM 4. CONTROLS AND PROCEDURES

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

Changes in internal control over financial reporting. There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On August 2, 2002, N.V. Euromedix (Euromedix) filed suit against us in the Commercial Court in Leuven, Belgium (No. F5700-02), seeking damages for the wrongful termination of an implied distribution agreement with our company for Europe and parts of the Middle East. On November 7, 2002, the court dismissed the suit. On December 31, 2002, Euromedix filed suit against us in the Commercial Court in Leuven, Belgium (No. F8756-02), seeking damages in the amount of approximately ∈3.5 million for the wrongful termination of an implied distribution agreement with our company for Europe and parts of the Middle East. A hearing was held on April 29, 2003 regarding certain procedural issues. In a judgment rendered on May 27, 2003, the court referred the complaint to the Constitutional Court before rendering a final decision. The court asked the Constitutional Court to render an opinion regarding certain constitutional issues related to the trademark infringement arguments we raised at the hearing. Hearings in the Constitutional Court were held on July 8, 2003 and September 9, 2003. The court has not yet rendered its opinion. We believe these claims are without merit and intend to continue to defend the claims vigorously.

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On December 23, 1999, Roche filed suit against us and two of our distributors, Health Care Solutions AG and Euromedix N.V./SA, in the Canton Court of the Canton Zug in Zug, Switzerland (No. ES580/1999), seeking a cease and desist order barring us from selling HDL assay single-use test cassettes in Switzerland. The complaint alleges that we violated a Roche European patent for HDL. On July 11, 2000, the court denied Roche s request for an injunction and ordered it to pay a portion of our legal fees. On May 2, 2002, in response to our motion, the court ruled that it did not have local jurisdiction over the matter and ordered Roche to pay our legal fees. Roche subsequently appealed the May 2, 2002 decision by the Canton Court of the Canton Zug. On October 7, 2002, the Swiss Federal Tribunal referred the matter back to the Canton Court but rejected the jurisdiction aspect of Roche s appeal.

In January 2000, Roche filed suit against us and two of our distributors, Micro-Medical GmbH and Euromedix N.V./SA, in the District Court in Dusseldorf, Germany (No. 4aO4/00), seeking a cease and desist order barring us from selling HDL single-use test cassettes in Germany. The complaint alleges we violated a Roche German priority patent for HDL by selling our single-use test cassette containing a HDL assay in Germany. On December 4, 2001, a hearing was held in Dusseldorf, Germany at which witnesses for Roche and our company testified. On October 29, 2002, the District Court held a hearing on the merits of the case. The court rendered its decision on December 19, 2002, ruling that (i) we are not allowed to further distribute HDL test cassettes which correspond to the German Roche patent, (ii) our distributors must destroy HDL products in their possession, (iii) we and our distributors are subject to unspecified damages based on all sales which occurred in Germany since December 8, 1995 and (iv) we and our distributors must pay the legal fees of the litigation. On January 10, 2003, we appealed this ruling with the Appeal Court in Dusseldorf.

On August 2, 2000, we filed suit against Roche in the Federal Patent Court in Munich, Germany (No. 3 Ni 40/00), seeking the nullification of Roche s German patent for measurement of HDL cholesterol. On December 6, 2001, a hearing was held on the merits of the nullification complaint. The court partially voided the Roche German patent while clarifying the remaining claim with additional restrictions. On February 20, 2002, we filed an appeal with the Federal Supreme Court.

In September 2000, Roche filed suit against us and one of our distributors in the Commercial Court in Vienna, Austria (No. Ei/Ti ROCH 04002), seeking a cease and desist order barring us from distributing HDL assay single-use test cassettes in Austria. The complaint alleges that we violated a Roche European patent for HDL. On August 9, 2002, the court ruled in our favor and dismissed the patent infringement claim.

On March 3, 2003, Roche Diagnostics Corporation and Roche Diagnostics GmbH filed suit against us in the United States District Court for the Southern District of Indiana (Indianapolis) (No. 03-CV-0303-LJM-WTL), seeking a preliminary and permanent injunction, damages and attorneys fees for patent infringement. We were served with the suit on June 30, 2003. The complaint alleges that we are violating three Roche U.S. patents for HDL. On July 21, 2003, we filed an answer and counter claim with the U.S. District Court for the Southern District of Indiana.

On December 19, 2003 we entered into a settlement agreement and license agreement with Roche Diagnostics Corporation and Roche Diagnostics GmbH in connection with ongoing patent infringement litigation. The settlement, which serves as the basis for the dismissal of all patent litigation between us and Roche on a worldwide basis, provides for us to make a $7 million payment to Roche, which we made on December 30, 2003. In addition, Roche agreed to grant an irrevocable, non-exclusive,

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worldwide license to us for its patents related to HDL cholesterol. As a part of this settlement, we will pay Roche an ongoing royalty that will be applied to only the HDL portion of cholesterol test cassettes we sell. Additionally the settlement agreement provides a mechanism for resolving any future patent infringement disputes. We believe that any such dispute resolution will confirm that our new HDL cholesterol test cassette, currently under development, does not infringe Roche s patents. If however, upon the resolution of any such dispute it is ultimately determined that our new HDL cholesterol test cassette is covered by Roche s patents, the we will pay the same ongoing royalty. As a result of the settlement, the parties have filed motions to dismiss the proceedings described above in the United States, Germany, Belgium, Switzerland and Austria.

We are also subject to various additional legal claims and assessments in the ordinary course of business, none of which are expected by management to result in a material adverse effect on the financial statements.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits.

10.45.1	First Amendment to Severance Agreement between Registrant and Timothy I. Still dated October 10, 2003
10.48.1	First Amendment to Severance Agreement between Registrant and Thomas E. Worthy dated October 10, 2003
10.51.1	First Amendment to Severance Agreement between Registrant and Donald P. Wood dated October 10, 2003
10.52	Change of Control Severance Agreement between Registrant and Donald P. Wood dated October 10, 2003
10.53	Change of Control Severance Agreement between Registrant and Timothy I. Still dated October 10, 2003
10.54	Change of Control Severance Agreement between Registrant and Thomas E. Worthy dated October 10, 2003
31.1	Certifications of Chief Executive Officer under Rule 13a-14(a)
31.2	Certifications of Chief Financial Officer under Rule 13a-14(b)
32.1	Certifications of Chief Executive Officer and Chief Financial Officer under Rule 13a-14(b)

(b) Reports on Form 8-K.

On October 22, 2003, we furnished a Current Report on Form 8-K reporting under Item 12 of Form 8-K that on October 22, 2003, we were issuing a press release and holding a conference call regarding our financial results for the fiscal quarter ended September 26, 2003.

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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.

CHOLESTECH CORPORATION

Date: February 5, 2004

/s/ Warren E. Pinckert II

Warren E. Pinckert II
President and Chief Executive Officer
(Principal Executive Officer)

Date: February 5, 2004

/s/ William W. Burke

William W. Burke
Vice President of Finance and Chief
Financial Officer
(Principal Financial and Accounting Officer)

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INDEX TO EXHIBITS

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