CHOLESTECH CORPORATION
Form 10-Q
January 31, 2005

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended December 24, 2004

o 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 such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes þ Noo

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).
Yesþ Noo

As of January 21, 2005, 14,359,485 shares of the registrant s common stock were outstanding.

CHOLESTECH CORPORATION
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PART I - FINANCIAL INFORMATION

ITEM 1. CONDENSED FINANCIAL STATEMENTS

CHOLESTECH CORPORATION

CONDENSED BALANCE SHEETS
(in thousands)

	December 24, 2004 (unaudited)	March 26, 2004(1)
Assets		
Current assets:		
Cash and cash equivalents	$ 4,349	$ 2,502
Marketable securities	15,928	11,300
Accounts receivable, net	2,978	6,038
Inventories, net	7,757	6,083
Prepaid expenses and other assets	1,755	1,715
Note receivable	50	200
Deferred tax assets	2,333	2,100
Total current assets	35,150	29,938
Property and equipment, net	8,249	8,257
Long-term investments	11,130	9,800
Long-term deferred tax assets	14,314	15,235
Total assets	$ 68,843	$ 63,230
Liabilities and Shareholders Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 4,647	$ 3,149
Accrued payroll and benefits	3,167	2,489
Other liabilities	268	314
Total current liabilities	8,082	5,952
Contingencies (note 9)		
Shareholders equity:		
	85,621	84,286

Common stock, no par value; 25,000,000 shares authorized; 14,359,485 and 14,095,075 shares issued and outstanding at December 24, 2004 and March 26, 2004, respectively		
Accumulated other comprehensive income (loss)	(42)	149
Accumulated deficit	(24,818)	(27,157)
Total shareholders equity	60,761	57,278
Total liabilities and shareholders equity	$ 68,843	$ 63,230

(1) The information in this column was derived from the Company s audited consolidated financial statements as of the fiscal year ended March 26, 2004.

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. 24, 2004	Dec. 26, 2003	Dec. 24, 2004	Dec. 26, 2003
Revenue	$ 14,573	$ 13,363	$ 37,663	$ 40,434
Cost of goods sold	5,771	6,166	15,499	17,328
Gross profit	8,802	7,197	22,164	23,106
Operating expenses:				
Sales and marketing	3,010	3,388	8,650	9,465
Research and development	1,181	754	3,055	2,360
General and administrative	2,346	2,238	7,179	6,411
Other operating costs				250
Litigation and other related		7,356		7,786
Total operating expenses	6,537	13,736	18,884	26,272
Income (loss) from operations	2,265	(6,539)	3,280	(3,166)
Interest and other income, net	60	62	118	271
Income (loss) before provision for income taxes	2,325	(6,477)	3,398	(2,895)
Current provision for income taxes	272	(648)	377	(290)
Deferred provision for income taxes	375	(1,878)	688	(839)
Provision (benefit) for income taxes	647	(2,526)	1,065	(1,129)
Income (loss) from continuing operations	1,678	(3,951)	2,333	(1,766)
Income from discontinued operations	1	5	6	29
Net income (loss)	$ 1,679	$ (3,946)	$ 2,339	$ (1,737)
Income (loss) from continuing operations per share:				
Basic	$ 0.12	$ (0.28)	$ 0.16	$ (0.13)
Diluted	$ 0.12	$ (0.28)	$ 0.16	$ (0.13)
Income (loss) from discontinued operations per share:				

Basic	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Diluted	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Net income (loss) per share:				
Basic	$ 0.12	$ (0.28)	$ 0.16	$ (0.13)
Diluted	$ 0.12	$ (0.28)	$ 0.16	$ (0.13)
Shares used to compute income per share:				
Basic	14,333	13,988	14,241	13,880
Diluted	14,377	13,988	14,359	13,880

See Notes to Condensed Financial Statements

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

	Thirty-nine Weeks Ended	
	Dec. 24, 2004	Dec. 26, 2003
Cash flows from operating activities:		
Net income (loss)	$ 2,339	$ (1,737)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	2,430	1,963
Change in allowance for losses on accounts receivable	(2)	72
Change in inventory reserve	(634)	160
Deferred tax asset	688	(1,288)
Changes in assets and liabilities:		
Accounts receivable	3,062	(1,236)
Inventories	(1,040)	489
Note receivable	150	
Prepaid expenses and other assets	(103)	319
Accounts payable and accrued expenses	1,498	6,884
Accrued payroll and benefits	678	608
Other liabilities	(46)	(34)
Net cash provided by operating activities	9,020	6,200
Cash flows from investing activities:		
Sales and maturities of marketable securities	19,160	38,893
Purchases of marketable securities	(25,246)	(42,689)
Purchases of property and equipment	(2,422)	(2,679)
Net cash used in investing activities	(8,508)	(6,475)
Cash flows from financing activities:		
Issuance of common stock	1,335	1,502
Net cash provided by financing activities	1,335	1,502
Net increase in cash and cash equivalents	1,847	1,227
Cash and cash equivalents at beginning of period	2,502	8,747
Cash and cash equivalents at end of period	$ 4,349	$ 9,974

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 an independent registered public accounting firm, and should be read in conjunction with the audited financial statements contained in the Annual Report on Form 10-K for the fiscal year ended March 26, 2004. 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 25, 2005.

2. Balance Sheet Data

The components of inventories are as follows (in thousands):

	December 24, 2004	March 26, 2004
Raw materials	$ 1,673	$ 1,954
Work-in-process	2,904	1,767
Finished goods	3,180	2,362
	$ 7,757	$ 6,083

3. 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. Included in the reclassification were certain legal costs from the twenty-six weeks ended September 26, 2003 relating to the Roche patent lawsuit which was originally classified as general and administrative and were reclassified as Litigation and other related costs. Additionally, certain costs relating to shared human resources and information technology were allocated to sales and marketing, development and general and administrative expenses. These shared costs are all now classified as general and administrative costs.

4. 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. As a result of the sale, the operations of WellCheck have been accounted for as discontinued operations in accordance with Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* and Accounting Principles Board (APB) Opinion No. 30,

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Reporting the Results of Operations-Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions.

The results of the Company s discontinued operations for the thirteen weeks ended and thirty-nine weeks ended December 24, 2004 and December 26, 2003 (in thousands of dollars) were as follows:

	Thirteen Weeks Ended		Thirty-nine Weeks Ended	
	Dec. 24, 2004	Dec. 26, 2003	Dec. 24, 2004	Dec. 26, 2003
Income before provision for income taxes	1	8	10	47
Income tax provision		3	4	18
Income	$ 1	$ 5	$ 6	$ 29

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

5. Derivative Financial Instruments

The Company uses financial instruments, such as forward exchange contracts, to hedge a portion of certain existing and anticipated foreign currency denominated transactions expected to occur within 12 months. The terms of currency instruments used for hedging purposes are generally consistent with the timing of the transactions being hedged. The Company enters into foreign currency forward exchange contracts to manage foreign currency exposures arising from inventory purchases and accounts payable denominated in foreign currencies. The Company does not use derivative financial instruments for trading or speculative purposes.

As of December 24, 2004, the Company had outstanding forward contracts to purchase £128,000 for approximately $236,000. The open contracts mature at various dates through April 15, 2005 and hedge certain forecasted inventory purchases denominated in the British Pound Sterling. The unrealized gain on the forward contracts as of December 24, 2004 was $10,000, all of which is expected to be reclassified to expense 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.

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6. Net Income Per Share

Basic earnings per share is computed by dividing net income (numerator) by the weighted average number of common shares outstanding (denominator) during the period. Diluted earnings per share gives effect to all potential common stock outstanding during a period, if dilutive. The following table reconciles the numerator (net income) and denominator (number of shares) used in the basic and diluted per share computations:

	Thirteen Weeks Ended		Thirty-nine Weeks Ended	
	Dec. 24, 2004	Dec. 26, 2003	Dec. 24, 2004	Dec. 26, 2003
(in thousands, except per share data)				
Income (loss)				
Income from continuing operations	$ 1,678	$ (3,951)	$ 2,333	$ (1,766)
Income from discontinued operations	1	5	6	29
Net income (loss)	$ 1,679	$ (3,946)	$ 2,339	$ (1,737)
Shares				
Basic	14,333	13,988	14,241	13,880
Effect of dilutive securities	44		118	
Diluted	14,377	13,988	14,359	13,880
Per share continuing operations:				
Basic	$ 0.12	$ (0.28)	$ 0.16	$ (0.13)
Effect of dilutive securities	0.00	0.00	0.00	0.00
Diluted	$ 0.12	$ (0.28)	$ 0.16	$ (0.13)
Per share discontinued operations:				
Basic	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Effect of dilutive securities	0.00	0.00	0.00	0.00
Diluted	$ 0.00	$ 0.00	$ 0.00	$ 0.00
Per share net income (loss)				
Basic	$ 0.12	$ (0.28)	$ 0.16	$ (0.13)
Effect of dilutive securities	0.00	0.00	0.00	0.00
Diluted	$ 0.12	$ (0.28)	$ 0.16	$ (0.13)

As of December 24, 2004, options to purchase 1,458,304 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. As of December 26, 2003, options to purchase 2,237,368 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.

7. Stock-Based Compensation

The Company accounts for its stock-based compensation plans in accordance with SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS 123) as amended by SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure* (SFAS 148). As permitted under SFAS 148, the Company uses the intrinsic value-based method of APB No. 25, *Accounting for Stock Issued to Employees* (APB 25), to account for its employee stock-based

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compensation plans. Under APB 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.

The Company provides additional proforma disclosures required by SFAS 123 as amended by SFAS 148. Had the compensation cost for the Company s stock option and stock purchase plans been determined based on the fair market value of the options at the grant dates, as prescribed in SFAS 123, the Company s net income and net income per share would have been as follows:

	Thirteen Weeks Ended		Thirty-nine Weeks Ended	
	Dec. 24, 2004	Dec. 26, 2003	Dec. 24, 2004	Dec. 26, 2003
(in thousands, except per share data)				
Net income (loss) as reported	$ 1,679	$ (3,946)	$ 2,339	$ (1,737)
Deduct: total stock-based employee compensation expense determined under fair value based method for all awards, net of tax	733	726	2,379	2,307
Pro forma net income (loss)	$ 946	$ (4,662)	$ (40)	$ (4,044)
Net income (loss) per share:				
Basic				
As reported	$ 0.12	$ (0.28)	$ 0.16	$ (0.13)
Pro forma	$ 0.07	$ (0.33)	$ 0.00	$ (0.29)
Diluted				
As reported	$ 0.12	$ (0.28)	$ 0.16	$ (0.13)
Pro forma	$ 0.07	$ (0.33)	$ 0.00	$ (0.29)

The pro forma information presented above for the thirteen and thirty-nine weeks ended December 26, 2003 has been revised from the information previously presented in the Company s Form 10-Q for the period ended December 26, 2003. 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.

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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. 24, 2004	Dec. 26, 2003	Dec. 24, 2004	Dec. 26, 2003
Stock Options:				
Expected volatility	73.42%	90.78%	74.91%	90.78%
Risk free interest rate	1.93%	1.06%	1.64%	1.05%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Fair value of stock options granted (per share)	$ 4.81	$ 6.22	$ 5.31	$ 7.11
Expected life	7 Years	7 Years	7 Years	7 Years
Stock purchase rights:				
Expected volatility	74.92%	90.78%	74.92%	90.78%
Risk free interest rate	1.69%	1.04%	1.69%	1.04%
Dividend yield	0.0%	0.0%	0.0%	0.0%
Fair value of stock purchase rights (per share)	$ 1.15	$ 1.35	$ 1.15	$ 1.35
Expected life	6 Months	6 Months	6 Months	6 Months

Under APB 25, compensation expense for grants to employees is based on the difference, if any, on the date of the grant, between the fair market value of the Company s stock and the option exercise price. SFAS 123 defines a fair value based method of accounting for an employee stock option or similar equity investment. The pro forma disclosure of the difference between compensation expense included in net income (loss) and the related cost measured by the fair value method is presented above.

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. B/02/00044), 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. At the introductory hearing on April 1, 2003, the case was sent to the general docket and there have been no further developments. The Company believes this claim is without merit and intends to continue to defend the claim vigorously.

On March 14, 2003, the Company initiated trademark infringement proceedings against Euromedix before the President of the Commercial Court in Leuven, Belgium (No. BRK/03/00017), seeking in principle an order (i) to prohibit Euromedix from selling, stocking, importing, exporting or promoting in the European Economic Area (EEA) products that violate the Company s trademarks, under a penalty of 10,000 for each LDX-Analyzer sold, a penalty of 1,000 Euros for each cassette sold contrary to the prohibition and 25,000 Euros penalty for each publicity of advertisement; (ii) to prohibit Euromedix from using certain slogans and

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phrases, in combination with products associated with certain of the Company s trademarks, in trade documents or other announcements, under a penalty of 25,000 for each document used contrary to this prohibition; and (iii) to order the destruction of the inventory of products held by Euromedix that violate the Company s trademarks, which have been imported into the EEA without the Company s permission.

A hearing was held on April 29, 2003 regarding certain procedural issues. In a judgment rendered on May 27, 2003, the Judge of Seizures of the Court of First Instance referred the complaint to the Constitutional Court before rendering a final decision. The Judge of Seizures 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. On March 24, 2004, the Constitutional Court issued its judgment which supported the Company s claims. A hearing was scheduled for November 9, 2004 by the Judge of Seizures of the Court of First Instance to hear additional submissions. On December 21, 2004, the Judge of Seizures of the Court of First Instance decided against Euromedix s opposition to certain procedural issues.

On March 26, 2004, a putative class action lawsuit captioned *Northshore Dermatology Center, S.C. v. Cholestech Corporation, and Does 1-10*, Case No. 04CH05342, was filed in the Circuit Court of Cook County, Illinois. The Company was served with the complaint and summons on March 31, 2004. The complaint alleges that the Company violated the federal Telephone Consumer Protection Act and various Illinois state laws by sending unsolicited advertisements via facsimile transmission to residents of Illinois. The complaint seeks class certification and statutory damages of $500 to $1,500 each on behalf of a class that would include all residents of Illinois who received an unsolicited facsimile advertisement from the Company. On January 18, 2005 the parties entered into an agreement to settle all claims on behalf of a nationwide class. Under the terms of the settlement, the Company will pay $625,000 in cash to settle all claims of which $600,000 will be funded by insurance. The Company has also agreed to pay up to $50,000 for providing notice to the class and for processing claims. The settlement is subject to Court approval.

The Company is 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.

9. Comprehensive Income (Loss)

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

	Thirteen Weeks Ended		Thirty-nine Weeks Ended	
	Dec. 24, 2004	Dec. 26, 2003	Dec. 24, 2004	Dec. 26, 2003
Net income (loss)	$ 1,679	$ (3,946)	$ 2,339	$ (1,737)
Change in unrealized gain on investments, net	(73)	(10)	(128)	(100)
Change in future currency contracts, net	(22)	28	(63)	153
Total comprehensive income (loss)	$ 1,584	$ (3,928)	$ 2,148	$ (1,684)

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10. Income Taxes

For the thirty-nine weeks ended December 24, 2004, the Company recorded a provision for income taxes of $1.1 million for an effective tax rate of 31.39%. The effective tax rate is less than the applicable federal and state tax rates due to a benefit of $195,000 relating to California manufacturers investment credit and research and development credit of $88,000. For the thirty-nine weeks ended December 26, 2003, the Company recorded a benefit from 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.

The realizability of the deferred tax assets is primarily dependent on the ability of the Company to generate income in the future. Subsequent changes in the Company s estimate of future profitability could require the Company to change its estimate of the realizability of its deferred tax assets and record a valuation allowance. Such a change in estimate would result in a material deferred tax expense in the period of change.

11. Warranties

The Company records an accrual for estimated warranty costs when revenue is recognized. Warranty covers repair costs of the LDX Analyzer and replacement costs of defective single-use test cassettes. The warranty period for the LDX Analyzer is one year and for single-use test cassettes is the shelf-life of the product. The warranty cost of the GDX Analyzer is 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 and repair costs, known design changes, 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 Company s product warranty liability during the thirty-nine weeks ended December 24, 2004 and December 26, 2003, respectively, were as follows (in thousands)

	Thirty-nine Weeks Ended	
	December 24, 2004	December 26, 2003
Balance at the beginning of the year	$ 314	$ 116
Accruals and charges for warranty for the year	545	346
Cost of repairs and replacements	(591)	(356)
Balance	$ 268	$ 106

12. Recent Accounting Pronouncements

In December 2004, the FASB issued SFAS 123R, *Share-Based Payment*, (SFAS 123R). This revised standard addresses the accounting for share-based payment transactions in which a company receives employee services in exchange for either equity instruments of the company or liabilities

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that are based on the fair value of the company s equity instruments or that may be settled by the issuance of such equity instruments. Under the new standard, companies will no longer be able to account for share-based compensation transactions using the intrinsic method in accordance with APB 25. Instead, companies will be required to account for such transactions using a fair-value method and recognize the expense in the consolidated statement of income. SFAS 123R will be effective for all interim or annual periods beginning after June 15, 2005. The Company will adopt this standard in June 2005 and is in the process of accessing the impact to the company.

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: plans for future sales and marketing expenditures; factors affecting our growth strategy for the physician office laboratory market; our beliefs with respect to sales to distribution partners and future revenue growth; our expectation regarding future sales of the GDX analyzer and related products; our expense forecasts for sales and marketing, research and development and general and administrative; our expectation for securities investment income; and our expected capital expenditures. 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 statements.

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 are a medical diagnostic company that develops, manufactures and markets products that perform diagnostic testing at sites outside of traditional hospital and clinical laboratories to assist in the assessment of the risk of heart disease, diabetes and certain liver diseases and in the monitoring of therapy to treat those diseases. Our products are sold worldwide. Our primary market is the U. S. physician laboratory market, which consists of approximately 104,000 sites that are registered with the Centers for Medicare & Medicaid Services (CMS), approximately 49,000 of which are registered to perform only tests that have been waived under the Clinical Laboratory Improvement Amendments (CLIA). In the thirteen weeks ended December 24, 2004 and first thirty-nine weeks of fiscal 2005, sales of our products to the physician office laboratory market represented 58% and 52% of our revenue,

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the health promotion represented 30% and 34% of our revenue and international represented 12% and 14%, respectively.

Our corporate headquarters are located in Hayward, California. All of our manufacturing, research, regulatory and administrative activities are conducted at this location. We sell our products through a worldwide network of over 85 distributors. We have 20 regional sales managers who coordinate and work with our distribution partners to identify and promote sales of our products. We also employ 17 field technical service representatives who are responsible for field customer service and customer retention initiatives within our existing installed base of products.

Revenue to the physician office laboratory market increased 6% and 8% during our second and third fiscal quarters of fiscal year 2005, respectively, and was 52% of our total sales for the thirty-nine weeks ended December 24, 2004. Given the expected continued growth in the number of CLIA waived physician office laboratories and in our estimated installed base of LDX Analyzers, we plan to continue to devote a majority of our sales and marketing expenditures toward increasing both our penetration of this market and the utilization of single-use disposable cassettes by our existing end-user physician customers. During the current fiscal year we have undertaken various promotional awareness programs and other initiatives to enhance the sales of our cassette products, which currently represent 81% of our revenue. We expect that the introduction and continued development of products which can be used on our existing LDX platform or another platform that could be CLIA waived and be sold to our installed base will be an important component of our growth strategy in the physician office laboratory market.

In the third quarter of fiscal year 2005, revenue of $14.6 million was 8% higher than the second quarter of fiscal year 2005 and 9% higher over the third quarter of fiscal year 2004. With two consecutive quarters of increasing revenue, we believe that sales to our distribution partners are now normalized and that the elimination of all quarter end discounts will no longer have an impact on our financial results. As a result, we expect revenue, in aggregate, for the second, third and fourth quarters of the fiscal year 2005 to grow in excess of 10% over the same period last year.

Beginning in January 2005, Medicare Section 612 - Cardiovascular Screening coverage went into effect as part of the larger Medicare Prescription Drug, Improvement, and Modernization Act of 2003. All Medicare beneficiaries now have access to preventive cholesterol screening blood tests for the early detection of cardiovascular disease and all new Medicare members will be covered for an initial physical examination. Both include the use of three tests to detect early risk for cardiovascular disease, including total cholesterol, a HDL-cholesterol, and a triglycerides test, which can be ordered as a lipid panel or individually. Although we believe the new guidelines will provide us with opportunities for future growth, it is premature to predict their impact on our business.

In December 2004, we signed a lease amendment agreement for our Hayward facility. Under the terms of the agreement, our lease has been extended by 10 years to March 31, 2017. This amendment reduces our average rent cost over the length of the lease, provides stability for our manufacturing process and avoids the expense of relocation. Our total future payments under the lease will be approximately $9.1 million. As a result of the lease extension, certain leasehold improvements have had their depreciable lives increased from the completion of the old lease to the new lease. This change in lives will result in a decline in depreciation expense of approximately $165,000 in fiscal year 2005, $495,000 in both fiscal year 2006 and fiscal year 2007.

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Results of Operations

The following table sets forth our results of operations (in thousands) 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					
	December 24, 2004		December 26, 2003		Amount of Increase (Decrease)	Percent Increase (Decrease)
	Amount	% of sales	Amount	% of sales		
Revenue	$ 14,573	100%	$ 13,363	100%	$ 1,210	9%
Cost of goods sold	5,771	40	6,166	46	(395)	(6)
Gross profit	8,802	60	7,197	54	1,605	22
Operating expenses						
Sales and marketing	3,010	21	3,388	25	(378)	(11)
Research and development	1,181	8	754	6	427	57
General and administrative	2,346	16	2,238	17	108	5
Other operating costs						
Litigation and other related			7,356	55	(7,356)	(100)
Total operating expenses	6,537	45	13,736	103	(7,199)	(52)
Income (loss) from operations	2,265	16	(6,539)	(49)	8,804	(135)
Interest and other income	60		62		(2)	(3)
Provision (benefit) for income taxes	647	4	(2,526)	(19)	3,173	126
Income from continuing operations	1,678	12	(3,951)	(30)	5,629	142
Gain from discontinued operations	1		5		(4)	(80)
Net income (loss)	$ 1,679	12%	$ (3,946)	(30)%	$ 5,625	(143)%

The following table provides information regarding our revenue (in thousands) for the three markets that we sell our products to and related revenue fluctuations for each such market for the thirteen weeks ended December 24, 2004:

	Thirteen Weeks Ended				
REVENUE BY MARKET	Dec. 24, 2004	Dec. 26, 2003	Dollar Change	Percentage Change	Percent of Total

Physician office laboratory	$ 8,396	$ 7,807	$ 589	8%	58%
Health promotion	4,362	3,669	693	19%	30%
International	1,815	1,887	(72)	(4)%	12%
TOTAL REVENUE	$ 14,573	$ 13,363	$ 1,210	9%	100%

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

	Thirty-nine Weeks Ended					
	December 24, 2004		December 26, 2003		Amount of Increase (Decrease)	Percent Increase (Decrease)
	Amount	% of sales	Amount	% of sales		
Revenue	$ 37,663	100%	$ 40,434	100%	$ (2,771)	(7)%
Cost of goods sold	15,499	41	17,328	43	(1,829)	(11)
Gross profit	22,164	59	23,106	57	(942)	(4)
Operating expenses						
Sales and marketing	8,650	23	9,465	23	(815)	(9)
Research and development	3,055	8	2,360	6	695	29
General and administrative	7,179	19	6,411	16	768	12
Other operating costs			250	1	(250)	(100)
Litigation and other related			7,786	19	(7,786)	(100)
Total operating expenses	18,884	50	26,272	65	(7,388)	(28)
Income (loss) from operations	3,280	9	(3,166)	(8)	6,446	204
Interest and other income	118		271	1	(153)	(56)
Provision (benefits) for income taxes	1.065	3	(1,129)	(3)	2,194	194
Income (loss) from continuing operations	2,333	6	(1,766)	(4)	4,099	232
Gain from discontinued operations	6		29		(23)	(79)
Net income (loss)	$ 2,339	6%	$ (1,737)	(4)%	$ 4,076	235%

The following table provides information regarding our revenue (in thousands) for the three markets that we sell our products to and related revenue fluctuations for each such market for the thirty-nine ended December 24, 2004:

	Thirty-Nine Weeks Ended				
REVENUE BY MARKET	Dec. 24, 2004	Dec. 26, 2003	Dollar Change	Percentage Change	Percent of Total
Physician office laboratory	$ 19,633	$ 22,617	$ (2,984)	(13)%	52%
Health promotion	12,707	12,213	493	4%	34%

International	5,323	5,603	(280)	(5)%	14%
TOTAL REVENUE	$ 37,663	$ 40,434	$ 2,771	7%	100%

Revenue. For the thirteen weeks ended December 24, 2004, revenue increased $1.2 million, or 9%, to $14.6 million from $13.4 million for the thirteen weeks ended December 26, 2003. The increase in revenue is primarily attributable to the sale of single-use test cassettes which increased $924,000, or 8%, from $11.2 million for the thirteen weeks ended December 26, 2003 to $12.2 million for the thirteen weeks ended December 24, 2004 primarily in the domestic markets. Revenue from sales of our LDX

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analyzer was $857,000 for the thirteen weeks ended December 24, 2004 as compared to $858,000 for the thirteen weeks ended December 26, 2003. Sales of accessories increased $318,000, or 44%, to $1.0 million for the thirteen weeks ended December 24, 2004 from $728,000 for the thirteen weeks ended December 26, 2003. Revenue from sales of our GDX analyzer and related single-use test cartridges decreased $31,000, or 6%, to $497,000 for the thirteen weeks ended December 24, 2004 from $528,000 for the thirteen weeks ended December 26, 2003. The decline in sales levels for both domestic and international GDX and related products was the result of our focus on lipid and products under development and business in light of pending Medicare reimbursement for cholesterol and diabetes screening which can be performed on the LDX. We anticipate this trend will continue at the current rate for the remainder of the fiscal year.

For the thirteen weeks ended December 24, 2004, domestic revenue increased $1.3 million or 11%, to $12.8 million from $11.5 million for the thirteen weeks ended December 26, 2003. On October 1, 2004, we increased our domestic list price of all our LDX related products by 3%, distributed among single-use cassettes, LDX and accessories domestic revenue which increased domestic revenue by approximately $350,000. Most of the domestic increase related to revenue from single-use test cassettes, which increased $1.0 million, or 10%, from $10.0 million the prior year period. The increase related to a 10% unit volume increase due to our efforts to expand cassette utilization through end-user direct contact programs. LDX revenue decreased $124,000, or 20%, to $503,000 due to a 16% unit volume decrease for the thirteen weeks ended December 24, 2004 from $627,000 for the thirteen weeks ended December 26, 2003. LDX revenue in the third quarter of fiscal 2004 was unusually large due to discounts offered at the end of quarter. Revenue for accessories increased $222,000, or 40%, to $776,000 for the thirteen weeks ended December 24, 2004 from $554,000 for the thirteen weeks ended December 26, 2003. We expect domestic revenue for the remainder of fiscal year 2005 and fiscal year 2006 to increase due to the release of our new ALT/AST test cassette, and increased testing on our installed base due to the recently enacted Medicare reimbursement for the screening of lipids for the Medicare population. Domestic revenue for our GDX Analyzer and related single-use test cartridges increased $155,000, or 53%, to $446,000 for the thirteen weeks ended December 24, 2004 from $291,000 for the thirteen weeks ended December 26, 2003.

International revenue decreased $72,000, or 4%, to approximately $1.8 million for the thirteen weeks ended December 24, 2004 from $1.9 million for the thirteen weeks December 26, 2003. Most of the revenue decline resulted from the sale of GDX and related products which decreased $186,000, or 78%, to $51,000 for the thirteen weeks ended December 24, 2004 from $237,000 for the thirteen weeks ended December 26, 2003. Single-use test cassettes which decreased $105,000, or 9%, to $1.1 million for the thirteen weeks ended December 24, 2004 from $1.2 million for the thirteen weeks ended December 26, 2003. This decrease was offset by LDX revenue which increased $123,000, or 53%, to $355,000 for the thirteen weeks ended December 24, 2004 from $231,000 for the thirteen weeks ended December 26, 2003. This increase related to pharmaceutical promotional programs to place LDX units in Europe. International revenue for accessories increased $96,000, or 55%, to $270,000 for the thirteen weeks ended December 24, 2004 from $174,000 for the thirteen weeks ended December 26, 2003. The overall decrease in international revenue was related to a reduction of orders from pharmaceutical companies in Latin America. International revenue is primarily related to pharmaceutical promotional programs which tend to occur in irregular patterns and are difficult to forecast. We expect the trend to continue but this will be partially offset by our increase to our international list price for LDX related products by 3% effective as of January 1, 2005.

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For the thirty-nine weeks ended December 24, 2004, revenue decreased $2.8 million, or 7%, to $37.7 million from $40.4 million for the thirty-nine weeks ended December 26, 2003. The decrease was primarily due to the impact of eliminating end of quarter discounts to our distributors. Most of the decrease related to a 13% decline in the physician office laboratory market. Sales of single-use test cassettes decreased $1.6 million, or 5%, from $32.8 million for the thirty-nine weeks ended December 26, 2003 to $31.2 million for the thirty-nine weeks ended December 24, 2004. Revenue for our LDX analyzer decreased $513,000, or 18%, to $2.4 million for the thirty-nine weeks ended December 24, 2004 from $2.9 million for the thirty-nine weeks ended December 26, 2003. The revenue decline was attributable to a promotion earlier in the year in which certain end-users were provided a free LDX when they purchased a predetermined number of single-use test cassettes from our distribution partners and lower sales during the first quarter of fiscal year 2005 related to the end of quarter end discounts to distribution partners. Revenue for our GDX analyzer and related single-use test cartridges decreased $692,000, or 32%, to $1.5 million for the thirty-nine weeks ended December 24, 2004, from $2.2 million for the thirty-nine weeks ended December 26, 2003. Accessories sales increased $72,000, or 3%, to approximately $2.6 million for both the thirty-nine weeks ended December 24, 2004 and the thirty-nine weeks ended December 26, 2003. The decline in GDX and related product revenue related to our decision to de-emphasize those products in order to focus on our lipid and products under development and business in light of Medicare reimbursement for cholesterol and diabetes screening which can be performed on the LDX.

For the thirty-nine weeks ended December 24, 2004, domestic revenue decreased $2.4 million, or 7%, to $32.4 million from $34.8 million for the thirty-nine weeks ended December 26, 2003. The decrease in revenue was primarily attributable to the elimination of end of quarter discounts to distributors. This resulted in a 13% total revenue decrease in the physician office laboratory market, which decreased $3.0 million to $19.6 million during the thirty-nine weeks ended December 24, 2004, from $22.6 million for the thirty-nine weeks ended December 26, 2003. Most of the decrease in domestic revenue related to revenue from single-use test cassettes which declined $1.1 million, or 4%, to $27.9 million for the thirty-nine weeks ended December 24, 2004 from $29.0 million for the thirty-nine weeks ended December 26, 2003. Revenue for the LDX analyzer decreased by $931,000, or 44%, to $1.2 million for the thirty-nine weeks ended December 24, 2004 form $2.1 million for the thirty-nine weeks ended December 26, 2003. Additionally, domestic revenue for our GDX analyzer and related single-use test cartridges, decreased $397,000, or 24%, to $1.3 million for the thirty-nine weeks ended December 24, 2004, from $1.7 million for the thirty-nine weeks ended December 26, 2003. The overall domestic revenue decline was attributable to lower sales during the first quarter of fiscal year 2005 due to the end of quarter end discounts to distribution partners and a promotion earlier in the year in which certain end-users were provided a free LDX when they purchased a predetermined number of single-use test cassettes from our distribution partners. The decline in GDX and related product revenue related to our decision to de-emphasize those products in order to focus on our lipid and pending products and business in light of Medicare reimbursement for cholesterol and diabetes screening which can be performed on the LDX.

International revenue decreased $279,000, or 5%, to $5.3 million for the thirty-nine weeks ended December 24, 2004 from $5.6 million for the thirty-nine weeks ended December 26, 2003. The decrease was primarily related to a reduction of orders from pharmaceutical companies in Latin America. International revenue is primarily related pharmaceutical promotional programs which tend to occur in irregular patterns and are difficult to forecast. Most of the decline related to the sale of single-use test cassettes which decreased $474,000, or 13%, to $3.3 million for the thirty-nine weeks ended December 24, 2004 from $3.8 million for the thirty-nine weeks ended December 26, 2003. This was

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offset by LDX revenue which increased $418,000, or 54%, to $1.2 million for the thirty-nine weeks ended December 24, 2004 from $779,000 for the thirty-nine weeks ended December 26, 2003. Additionally, international revenue for our GDX and related products decreased $296,000, or 59%, to $207,000 for the thirty-nine weeks ended December 24, 2004, from $503,000 for the thirty-nine weeks ended December 26, 2003. International revenue is primarily related to pharmaceutical promotional programs which tend to occur in irregular patterns and are difficult to forecast.

Cost of Goods Sold. Cost of goods sold includes direct labor, direct material, overhead and royalties. Cost of goods sold decreased $395,000, or 6%, to $5.8 million for the thirteen weeks ended December 24, 2004 from $6.2 million for the thirteen weeks ended December 26, 2003. Most of the decrease related to factory spending which decreased $207,000, or 5%, for the thirteen weeks ended December 24, 2004 compared to the thirteen weeks ended December 26, 2003. A shift in product mix to more single-use test cassette content further reduced cost of goods sold by $131,000. In addition, the improvements in factory efficiencies reduced cost of goods sold by $58,000. Gross margins were 60% and 54% for the thirteen weeks ended December 24, 2004 and December 26, 2003. Reduced factory spending and increased factory efficiencies improved gross margin by 3%. A 3% price increase for domestic LDX and related products, effective as of October 1, 2004, increased gross margin by approximately $350,000, or 2%. The balance of the improvement in gross margin related to a shift in product mix towards our single-use test cassettes, which are our highest margin products and improved production efficiencies.

The factory spending decrease was primarily due to material scrap, which decreased $378,000 from $565,000 for the thirteen weeks ended December 26, 2003 to $187,000 for the thirteen weeks ended December 24, 2004, as a result of improvements in factory process controls. Wages and other related costs decreased by $145,000 due to reductions in overtime for the thirteen weeks ended December 24, 2004, compared to the thirteen weeks ended December 26, 2003. Additionally, repairs and maintenance costs decreased by $52,000 compared to the prior year. Royalty spending increased by $208,000, or 56%, due to the agreement with Roche relating to HDL products. As a part of the settlement agreement with Roche, we agreed to pay starting in December 2003 what we believe is a reasonable ongoing royalty that is applied to only the HDL portion of cholesterol test cassettes we sell. These payments, along with any future royalty payments, are charged to cost of goods sold as incurred.

For the thirty-nine weeks ended December 24, 2004, cost of goods sold decreased $1.8 million, or 11%, to $15.5 million from $17.3 million for the thirty-nine weeks ended December 26, 2003. The decrease in cost of goods sold primarily related to a decline in product shipped due to the 7% decrease in revenue. As a percentage of sales, the gross margins were 59% and 57% for the thirty-nine weeks ended December 24, 2004 and December 26, 2003, respectively. The improvement in gross margin related to the shift in product mix toward single-use cassettes, which are our highest margin products. Factory spending increased 1% for the thirty-nine weeks ended December 24, 2004, compared to the thirty-nine weeks ended December 26, 2003. The increase was primarily due to royalty payments on HDL paid to Roche which increased $751,000. Additionally, warranty increased by $352,000 and depreciation increased by $131,000. This was offset by inventory scrap which decreased by $1.0 million due to improvements in the manufacturing process which improved the yield during the production of single-use test cassettes.

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 decreased $378,000, or 11%, to $3.0 million for the thirteen weeks ended December 24, 2004

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from $3.4 million for the thirteen weeks ended December 26, 2003. The decline was mainly attributable to $261,000 decrease in wages and related spending, which was the result of a revision to the commission plan from the prior year. This was offset by increased wages for telemarketing programs. Additionally travel decreased $69,000 and package delivery charges decreased $64,000. As a percent of total revenue, sales and marketing expenses decreased to 21% for the thirteen weeks ended December 24, 2004 from 25% for the thirteen weeks ended December 26, 2003. Over the balance of the fiscal year, we expect sales and marketing expenses to remain constant or slightly decline as a percentage of total revenue.

For the thirty-nine weeks ended December 24, 2004, sales and marketing expenses decreased $815,000, or 9%, to $8.7 million from $9.5 million for the thirty-nine weeks ended December 26, 2003. A decline of $915,000 in product marketing expenses including product sample, advertising and market research was the primary reason for the decrease. Additionally, travel costs decreased by $275,000. This was partially offset by wages, commissions and related costs which increased by $255,000 and employee costs, including recruiting and relocation, which increased by $91,000. As a percent of total revenue, sales and marketing expenses were 23% for both the thirty-nine weeks ended December 24, 2004 and the thirty-nine weeks ended December 26, 2003.

Research and Development Expenses. Research and development expenses include salaries, bonuses, professional consulting service expenses, supplies and depreciation of capital equipment. Research and development expenses increased $427,000, or 57%, to $1.2 million, for the thirteen weeks ended December 24, 2004 from $754,000 for the thirteen weeks ended December 26, 2003. The increase was mainly attributable to higher wages and related cost which increased $223,000. Material used in the development of new products increased by $78,000, cost related to new product labeling increased $58,000, and employee costs relating to head count additions increased $29,000. All of these increases related to increased activities in new product development, including AST, hs-CRP, lipid profile with ALT and direct LDL. As a percent of total revenue, research and development expenses increased to 8% for the thirteen weeks ended December 24, 2004 from 6% for the thirteen weeks ended December 26, 2003. Over the balance of the fiscal year we expect research and development expenses to remain constant or increase as a percentage of total revenue.

For the thirty-nine weeks ended December 24, 2004, research and development expenses increased $695,000, or 29%, to $3.1 million from $2.4 million for the thirty-nine weeks ended December 26, 2003. The increased spending related primarily to higher headcount and associated wages, benefits and allocated facilities which were connected to new product development. Outside consultants costs related to new product development also increased. As a percent of total revenue, research and development expenses increased to 8% for the thirty-nine weeks ended December 24, 2004 from 6% for the thirty-nine weeks ended December 26, 2003.

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 $108,000 to $2.3 million for the thirteen weeks ended December 24, 2004 from $2.2 million for the thirteen weeks ended December 26, 2003. Outside professional services increased by $269,000 related to higher fees for outside accounting services primarily due to increased regulatory requirements for compliance to the Sarbanes-Oxley Act of 2002. Additionally, wages and related costs increased $193,000, due to increased staffing and benefits costs. This increase was offset by lower insurance premiums primarily for directors and officers insurance. As a percent of total revenue, general and administrative expenses decreased to 16% for the

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thirteen weeks ended December 24, 2004 from 17% for the thirteen weeks ended December 26, 2003. Over the balance of the fiscal year we expect general and administrative expenses to remain constant or decrease slightly as a percentage of total revenue.

For the thirty-nine weeks ended December 24, 2004, general and administrative expenses increased $768,000, or 12%, to $7.2 million from $6.4 million for the thirty-nine weeks ended December 26, 2003. This increase was primarily attributable to $491,000 increase in costs associated with outside professional services and consulting, including accounting support, which primarily related to $470,000 increase in compliance cost for the Sarbanes-Oxley Act of 2002. Additionally, bonuses and other benefit related costs increased $566,000 relating to obtaining anticipated management goals, higher benefit cost structure and increased head count. This increase was offset by lower insurance premiums including directors and officers liability insurance premiums, which decreased $386,000. As a percent of total revenue, general and administrative expenses increased to 19% for the thirty-nine weeks ended December 24, 2004 from 16% for the thirty-nine weeks ended December 26, 2003.

Other Operating Costs. For the thirteen weeks and 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 24, 2004. This cost related to the write-off of an option to purchase a patent which we determined no longer had an economic value.

Litigation and Other Related Expenses. For the thirteen weeks and thirty-nine weeks ended December 26, 2003, litigation and related expenses were $7.4 million and $7.8 million, respectively. There were no corresponding costs for the thirteen weeks and thirty-nine weeks ended December 24, 2004. These amounts related to our settlement with Roche in connection with ongoing patent infringement litigation. As a part of this settlement, we agreed to pay what we believe is a reasonable ongoing royalty that is applied to only the HDL portion of cholesterol test cassettes we sell. These payments, along with any future royalty payments, are charged to costs of good sold as they are incurred.

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, net of expenses, decreased $2,000, or 3%, to $60,000 for the thirteen weeks ended December 24, 2004 from $62,000 for the thirteen weeks ended December 26, 2003. We expect income from securities investments to continue at the current rate until securities mature and the market yield on reinvested securities increase.

For the thirty-nine weeks ended December 24, 2004 interest income, net of expenses, decreased $153,000, or 56%, to $118,000 from $271,000 for the thirty-nine weeks ended December 26, 2003. Most of the decrease related to the gain and loss from the sale of securities. For the thirty-nine weeks ended December 24, 2004 we recorded a loss of $9,000, compared to a gain of $127 for the thirty-nine weeks ended December 26, 2003.

Income Taxes. For the thirty-nine weeks ended December 24, 2004, the Company recorded a provision for income taxes of $1.1 million for an effective tax rate of 31.39%. The effective tax rate is less than the applicable federal and state tax rates due to a benefit of $195,000 relating to California manufacturers investment credit and research and development credit of $88,000. For the thirty-nine weeks ended December 26, 2003, the Company recorded a benefit from income taxes of $1.1 million,

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primarily resulting from the increase in the value of the net operating losses arising from the loss in the period.

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 in December 2002. The net gain on discontinued operations of $1,000 for the thirteen weeks ended December 24, 2004 compared to the net gain of $5,000 for the thirteen weeks ended December 26, 2003, was primarily attributable to royalties related to TEAMS software. For the thirty-nine weeks ended December 24, 2004, the net gain from discounted operations decreased $23,000 to $6,000 from $29,000 and was also attributable to royalties related to TEAMS software.

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

Cash flow information for the thirty-nine weeks ended December 24, 2004 and December 26, 2003 was as follows (in thousands):

	December 24, 2004	December 26, 2003
Cash, cash equivalents, marketable securities and long-term investments	$ 31,407	$ 31,157
Net cash provided by operating activities	9,020	6,200
Net cash used in investing activities	(8,508)	(6,475)
Net cash provided by financing activities	1,335	1,502
Net increase in cash and cash equivalents	$ 1,847	$ 1,227

We have financed our operations primarily through the sale of equity securities, including employee stock option exercises, and net cash provided by operations. From our inception to December 24, 2004, we have raised $85.6 million in net proceeds from equity financings. In addition to these amounts, we have available a $4.0 million revolving bank line of credit agreement which was renewed in August 2004 and will expire in September 2006. While the agreement 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 1.25% above the LIBOR rate, depending on the payment schedule. There are currently no amounts outstanding under this line of credit and as a result, there were no limitations on our deposited assets.

Cash Provided by Operating Activities. The net cash provided by operations increased $2.8 million to $9.0 million for the thirty-nine weeks ended December 24, 2004 from $6.2 million for the thirty-nine weeks ended December 26, 2003. Net cash provided by operations was primarily attributable to net income of $2.3 million and $2.5 million of non-cash adjustments including depreciation. A decline in working capital, other than cash, provided an additional $4.1 million in cash. Accounts receivables decreased by $3.1 million due to more consistent distribution of revenue within the fiscal year brought

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about by ending discounts at the end of the quarter. Additionally prepaid expenses and other assets declined $103,000, due to a reduction in prepaid insurance premiums. This was offset by $1.0 million inventory increase for single-use test cassettes which related to projected future demand over the balance of the fiscal year.

For the thirty-nine weeks ended December 26, 2003, net cash provided by operations was $6.2 million due to a $6.9 million increase in accounts payable, relating to the settlement of the Roche lawsuit. Payroll and other benefit liabilities increased by $608,000. Inventory decrease by $489,000 and prepaid expenses and other assets decreased by $319,000. This was offset $1.7 million of net loss, less $907,000 of non-cash adjustments, including depreciation and a decrease in deferred tax asset. Additionally, accounts receivable increased by $1.2 million due to a larger portion of revenue late in the third quarter of fiscal year 2004.

Cash Used in Investing Activities. Investing activities resulted in the net use of $8.5 million of cash during the thirty-nine weeks ended December 24, 2004. Spending on additional manufacturing equipment, facilities improvements and software accounted for $2.4 million of capital improvements, as well as a $6.1 million purchase of marketable securities during the period. Over the remainder of the current fiscal year, we intend to spend approximately $1.5 million on additional capital expenditures for production equipment and other long lived assets.

Investing activities resulted in the net use of $6.5 million of cash during the thirty-nine weeks ended December 26, 2003. Spending on additional manufacturing equipment and software accounted for $2.7 million of capital improvements, as well as a $3.8 million purchase of marketable securities during the period.

Cash Provided by Financing Activities. Cash provided by financing activities for both the thirty-nine weeks ended December 24, 2004 and December 26, 2003 related to the issuance of common stock pursuant to employee stock incentive plans. We raised $1.3 million and $1.5 million from the incentive programs for the thirty-nine weeks ended December 24, 2004 and December 26, 2003, respectively.

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.

Revenue Recognition

We recognize revenue from product sales when there is pervasive evidence that an arrangement exists, title has transferred to our customers, the price is fixed and determinable and collection is reasonably assured. Provisions for discounts to customers, returns are recorded as a reduction of revenue and provided for in the same period that the related product sales are recorded based upon analyses of historical discounts and returns. We recognize revenue associated with services upon

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completion of the services to be performed under contract when all obligations are satisfied, and collection is reasonably assured. If all conditions to recognize revenue are not met, we are required to defer revenue recognition.

We have made no other changes to the disclosure of 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 26, 2004.

Recent Accounting Pronouncements

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) 123R, *Share-Based Payment*, (SFAS 123R). This revised standard addresses the accounting for share-based payment transactions in which a company receives employee services in exchange for either equity instruments of the company or liabilities that are based on the fair value of the company s equity instruments or that may be settled by the issuance of such equity instruments. Under the new standard, companies will no longer be able to account for share-based compensation transactions using the intrinsic method in accordance with APB 25. Instead, companies will be required to account for such transactions using a fair-value method and recognize the expense in the consolidated statement of income. SFAS 123R will be effective for all interim or annual periods beginning after June 15, 2005. We will adopt this standard in June 2005 and are in the process of accessing the impact to our company.

In November 2004, FASB issued SFAS No. 151 *Inventory Costs An Amendment of ARB No. 43*. SFAS clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs and wasted material (spoilage). This standard will be effective for all fiscal years beginning after June 15, 2005. We will adopt this standard in our fiscal year beginning April 1, 2006 and do not anticipate the adoption of this standard will have a material impact on our financial statements.

Factors Affecting Future Operating Results

We have a history of 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 24, 2004, we had an accumulated deficit of $24.8 million. Our first profitable quarter was the third quarter of fiscal year 1998, and our first profitable year was fiscal 1998. We recorded a net profit of $5.6 million for fiscal year 2002, a net profit of $4.9 million for fiscal year 2003 and a net profit of $8.7 million for fiscal year 2004. 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;
- manufacturing problems, efficiencies, capacity constraints or delays;
- the timing of the introduction, availability and market acceptance of new tests and products;
- changes in demand for our products based on changes in third-party reimbursement policies, changes in government regulation and other factors;

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product pricing and discounts;

the timing and level of expenditures associated with research and development activities;

the timing, establishment and maintenance of strategic distribution arrangements and the success of the activities conducted under such arrangements;

the timing of significant orders from, and shipments to, customers;

competition from diagnostic companies with greater financial capital and resources;

costs and timing associated with business development activities, including potential licensing of technologies or intellectual property rights;

additions or departures of our key personnel;

promotional program spending by both domestic and European pharmaceutical companies;

variations in the mix of products sold; and

litigation or the threat of litigation.

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;

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

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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, in fiscal year 2004, 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 $7.0 million 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 trade secrets, or be capable of protecting our rights 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 negotiate to obtain licenses for new products. Some of our current licenses are subject to rights of termination and may be terminated. Our licensors may not abide by their contractual obligations and, as a result, may limit the benefits we currently derive from their licenses. We may be unable to renegotiate or 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

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obtain, maintain or enforce necessary licenses on commercially reasonable terms or to identify and implement alternative approaches could prevent us from introducing our products and severely harm our business.

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. For example, between March 28, 2003 and March 26, 2004, the price of our common stock, as reported on the NASDAQ National Market System, has ranged from a low of $6.20 to a high of $12.89. 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;

litigation or threat of litigation;

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;

our failure to achieve, or changes in, financial estimates by securities analysts and comments or opinions about us by;

securities analysts or major shareholders;

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.

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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:

- third-party payors are increasingly scrutinizing and challenging the prices charged for both existing and new 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.

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 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

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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 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. The discontinuation of promotional goods or pricing concessions could have a negative effect on our business. Our distributors could also modify their business practices, such as payment terms, inventory levels or order patterns.

For example, as part of our practice of providing periodic promotional incentives to our distribution partners, we have historically offered small discounts from standard distributor pricing to such partners in connection with large unit volume purchases. Throughout the course of fiscal year 2004, we experienced increasing demand by our distribution partners to purchase at such discounts toward the end of each quarter. We became increasingly concerned about the future impact on end-user pricing and the inefficiencies in our operations that result from month to month swings in shipping volume. As a result, beginning in the fourth quarter of fiscal year 2004, we decided to reduce the amount of product we sold to our distribution partners at a discount to their standard price. In the first, second and third quarters of fiscal year 2005, we did not grant any quarter-end discounts to our distributions partners. This change in business practice had a negative impact on our revenue in both the fourth quarter of fiscal year 2004 and the first quarter of fiscal year 2005. 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.

We may be unable to accurately predict future sales through our distributors, which could harm our ability to efficiently manage our internal resources to match market demand

Our product sales are primarily made through our network of over 85 domestic and international distributors. As a result, our financial results, quarterly product sales, trends and comparisons are affected by fluctuations in the buying patterns of end-user customers and our distributors, and by the changes in inventory levels of our products held by these distributors. We have only limited visibility over the inventory levels of our products held by our domestic and international distributors. While we attempt to assist our distributors in maintaining targeted stocking level of our products, we may not consistently be accurate or successful. This process involves the exercise of judgment and use of

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assumptions as to future uncertainties including end-user customer demand, and the reaction of our distributors to our current quarterly pricing policy. Consequently, actual results could differ from our estimates. Inventory levels of our products held by our distributors may exceed or fall below the levels we consider desirable on a going-forward basis, which may harm our financial results due to unexpected buying patterns of our distributors or our ability to efficiently manage or invest in internal resources, such as manufacturing and shipping capacity, to meet the actual demand for our products.

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 that use automated testing systems, as well as manufacturers of other rapid diagnostic tests. 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 cost effective and time saving alternatives to other rapid diagnostic tests 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, including Polymer Technology Systems, Inc. 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.

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

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

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

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 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 and introduce new tests and products to the market, our business will not grow 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

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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. In addition, our business strategy includes entering into agreements with clinical and commercial collaborators and other third parties for the development, clinical evaluation and marketing of existing products and products under development. These agreements may be subject to rights of termination and may be terminated without our consent. The parties to these agreements also may not abide by their contractual obligations to us and may discontinue or sell their current lines of business. Research performed under a collaboration for which we receive or provide funding may not lead to the development of products in the timeframe expected, or at all. If these agreements are terminated earlier than expected, or if third parties do not perform their obligations to us properly and on a timely basis, we may not be able to successfully develop new products as planned, or at all.

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;

human error;

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 could increase;

the custom nature of much of our manufacturing equipment increases the time required to remedy equipment failures and replace equipment;

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

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our new manufacturing line is operating at 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 manufacture the majority of our dry chemistry cassettes on a single production line. A second manufacturing line is currently used for overflow production and 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 year 2004 and 14% in fiscal year 2003. 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;

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.

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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 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 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 year 2004. In fiscal year 2004, Physicians Sales and Service (PSS) accounted for approximately 23% of our total revenue, Henry Schein Inc. (Henry Schein) accounted for approximately 9% and McKesson Medical Surgical (McKesson) accounted for 8% of our total revenue. In fiscal 2003, PSS accounted for approximately 22% of our total revenue, McKesson accounting for 9% of our total revenue, and Henry Schein accounted for approximately 7% 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.

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In the event we are unable to satisfy regulatory requirements relating to internal controls, or if these internal controls over financial reporting are not effective, our business and our stock price could suffer.

Section 404 of Sarbanes-Oxley requires companies to do a comprehensive and costly evaluation of their internal controls. As a result, during our fiscal year ending March 25, 2005, we will be required to perform an evaluation of our internal controls over financial reporting and have our auditor publicly attest to such evaluation. We have prepared an internal plan of action for compliance, which includes a timeline and scheduled activities with respect to preparation of such evaluation. Our efforts to comply with Section 404 and related regulations regarding our management s required assessment of internal control over financial reporting and our independent auditors attestation of that assessment has required, and continues to require, the commitment of significant financial and managerial resources. While we anticipate being able to fully implement the requirements relating to internal controls and all other aspects of Section 404 in a timely fashion, we cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or the impact of the same on our operations since there is no precedent available by which to measure compliance adequacy. If we fail to timely complete this evaluation, or if our auditors cannot timely attest to our evaluation, we could be subject to regulatory investigations or sanctions, costly litigation or a loss of public confidence in our internal controls, which could have an adverse effect on our business and our stock price.

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:

- 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.

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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 and AST test cassettes, 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 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, 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;

EN46001/ ISO9001/ ISO13485 requirements, which is an industry standard for maintaining and assuring conformance to quality standards; and

Medical Device Directive, 98/79/EC-1988 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.

Although in recent times there have been signs of a general economic upturn in the United States, it is uncertain as to how strongly this upturn may impact our markets over the next year

The primary customers for our products are physician office laboratories and entities conducting health promotion programs. Beginning in 2001, a general economic downturn in the United States reduced demand for our products and our customers capital spending in most of the markets that we serve. This general economic downturn continued through 2003 but has stabilized throughout 2004. However, it is uncertain as to how strongly this general economic upturn may impact the markets we

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serve over the next year and whether the upturn can be sustained. Overall, our customers spending decisions are still being closely scrutinized. Any future 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 again likely result in a decline in demand for our products and could adversely affect our business.

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 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.

Our business could be negatively affected by the loss of key personnel or our inability to hire qualified personnel

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.

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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.

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 anti-takeover plan. The issuance of

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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.

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.

Generally we hold our marketable securities until maturity. These securities have maturity dates that do not exceed fiscal year 2008 and have predominately fixed interest rates. We have concluded that the income on our investments would not be significantly impacted by short-term changes in interest rates. When the securities mature and the principal is reinvested, the yield will reflect the market conditions at that time. Fluctuations in short-term interest rates may change the fair market value of our investments; however, as the marketable securities approach maturity, the fair value will approximate our cost basis.

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 24, 2004, we had outstanding forward contracts to purchase £204,000 for approximately $378,000. The open contracts mature at various dates through March 15, 2005 and hedge certain forecasted inventory purchases denominated in the British Pound Sterling. The unrealized loss on the forward contracts as of December 24, 2004 was $5,000, all of which is expected to be reclassified to expense 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.

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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 (in thousands)	2005	2006	2007	Total	Fair Value
Cash, cash equivalents	$ 4,349	$	$	$ 4,349	$ 4,349
Short-term marketable securities	$ 5,560	$ 14,716	$	$ 20,276	$ 20,276
Weighted average interest rate	2.65%	3.31%			
Long-term marketable securities		$ 4,652	$ 6,477	$ 11,129	$ 11,129
Weighted average interest rate		4.16%	3.39%		

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.

Sarbanes-Oxley Section 404 Compliance. Section 404 of the Sarbanes-Oxley Act of 2002 (the Act) will require our company to include an internal control report from management in its Annual Report on Form 10-K for the fiscal year ending March 25, 2005 and in subsequent Annual Reports thereafter. The internal control report must include the following: (1) a statement of management s responsibility for establishing and maintaining adequate internal control over financial reporting, (2) a

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statement identifying the framework used by management to conduct the required evaluation of the effectiveness of our internal control over financial reporting, (3) management s assessment of the effectiveness of our internal control over financial reporting as of March 25, 2005, including a statement as to whether or not internal control over financial reporting is effective, and (4) a statement that our independent auditors have issued an attestation report on management s assessment of internal control over financial reporting.

Management acknowledges its responsibility for establishing and maintaining internal controls over financial reporting and seeks to continually improve those controls. In addition, in order to achieve compliance with Section 404 of the Act within the required timeframe, we have been conducting a process to document and evaluate our internal controls over financial reporting since December 2003. In this regard, we have dedicated internal resources, engaged outside consultants and adopted a detailed work plan to: (i) assess and document the adequacy of internal control over financial reporting; (ii) take steps to improve control processes where required; (iii) validate through testing that controls are functioning as documented; and (iv) implement a continuous reporting and improvement process for internal control over financial reporting. We believe our process for documenting, evaluating and monitoring our internal control over financial reporting is consistent with the objectives of Section 404 of the Act.

During the calendar year 2004, we commenced testing of our internal controls. At this time, given the risks inherent in the design and operation of internal controls over financial reporting, we can provide no assurance as to our, or our independent registered public accounting firm s conclusions at March 25, 2005 with respect to the effectiveness of our internal controls 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. B/02/00044), 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. At the introductory hearing on April 1, 2003, the case was sent to the general docket and there have been on further developments. We believe this claim is without merit and intend to continue to defend the claim vigorously.

On March 14, 2003, we initiated trademark infringement proceedings against Euromedix before the President of the Commercial Court in Leuven, Belgium (No. BRK/03/00017), seeking in principle an order (i) to prohibit Euromedix from selling, stocking, importing, exporting or promoting in the European Economic Area (EEA) products that violate our trademarks, under a penalty of 10,000 for each LDX Analyzer sold, a penalty of 1,000 for each cassette sold contrary to the prohibition and a 25,000 penalty for each publicity of advertisement for such products; (ii) to prohibit Euromedix from using certain slogans and phrases, in combination with products associated with certain of our trademarks, in trade documents or other announcements, under a penalty of 25,000 for each document used contrary to this prohibition; and (iii) to order the destruction of the inventory of products held by Euromedix that violate our trademarks, which have been imported into the EEA without our permission.

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A hearing was held on April 29, 2003 regarding certain procedural issues. In a judgment rendered on May 27, 2003, the Judge of Seizures of the Court of First Instance referred the complaint to the Constitutional Court before rendering a final decision. The Judge of Seizures 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. On March 24, 2004, the Constitutional Court issued its judgment which supported our claims. A hearing was scheduled for November 9, 2004 by the Judge of Seizures of the Court of First Instance to hear additional submissions. On December 21, 2004, the Judge of Seizures of the Court of First Instance decided against Euromedix s opposition to certain procedural issues.

On March 26, 2004, a putative class action lawsuit captioned *Northshore Dermatology Center, S.C. v. Cholestech Corporation, and Does 1-10*, Case No. 04CH05342, was filed in the Circuit Court of Cook County, Illinois. We were served with the complaint and summons on March 31, 2004. The complaint alleges that we violated the federal Telephone Consumer Protection Act and various Illinois state laws by sending unsolicited advertisements via facsimile transmission to residents of Illinois. The complaint seeks class certification and statutory damages of $500 to $1,500 each on behalf of a class that would include all residents of Illinois who received an unsolicited facsimile advertisement from us. On January 18, 2005 the parties entered into an agreement to settle all claims on behalf of a nationwide class. Under the terms of the settlement, we will pay $625,000 in cash to settle all claims, $600,000 of which will be funded by insurance. We had also agreed to pay up to $50,000 for providing notice to the class and for processing claims. The settlement is subject to Court approval.

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

31.1 Certifications of Chief Executive Officer under Rule 13a-14(a)

31.2 Certifications of Chief Financial Officer under Rule 13a-14(a)

32 Certifications of Chief Executive Officer and Chief Financial Officer under Rule 13a-14(b)

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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: January 31, 2004

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

Date: January 31, 2004

/s/ John F. Glenn
John F. Glenn
Vice President of Finance and Chief Financial Officer
(Principal Financial and Accounting Officer)

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INDEX TO EXHIBITS

Exhibit No.	Description
31.1	Certifications of Chief Executive Officer under Rule 13a-14(a)
31.2	Certification of Chief Financial Officer under Rule 13a-14(b)
32	Certification of Chief Executive and Chief Financial Officer under Rule 13a-14(b)