CHOLESTECH CORPORATION
Form 10-Q
August 07, 2003

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

FORM 10-Q

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 27, 2003

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission File Number: 000-20198

CHOLESTECH CORPORATION

(Exact name of registrant as specified in its charter)

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

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

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

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

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

As of July 31, 2003, 13,847,115 shares of the registrant s common stock were outstanding.

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PART I - FINANCIAL INFORMATION

ITEM 1. CONDENSED FINANCIAL STATEMENTS

CHOLESTECH CORPORATION

CONDENSED BALANCE SHEETS
(in thousands)

	June 27, 2003	March 28, 2003 (1)
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 12,593	$ 8,747
Marketable securities	2,436	4,776
Accounts receivable, net	6,121	5,195
Inventories, net	6,813	6,806
Note receivable	250	250
Prepaid expenses	1,685	1,989
Deferred tax assets	2,100	2,100
Total current assets	31,998	29,863
Property and equipment, net	7,728	7,491
Long-term investments	11,844	12,558
Long-term deferred tax assets	1,357	2,100
Total assets	$ 52,927	$ 52,012
Liabilities and Shareholders Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,607	$ 3,971
Accrued payroll and benefits	2,430	3,173
Other liabilities	119	140
Total current liabilities	6,156	7,284
Contingencies (note 8)		
Shareholders equity:		
Common stock, no par value; 25,000,000 shares authorized; 13,836,782 and 13,579,108 shares issued and outstanding at June 27, 2003 and June 28, 2002, respectively	82,983	82,242
Accumulated other comprehensive income	91	73
Accumulated deficit	(36,303)	(37,587)
Total shareholders equity	46,771	44,728
Total liabilities and shareholders equity	$ 52,927	$ 52,012

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

See Notes to Condensed Financial Statements

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

	Thirteen Weeks Ended	
	June 27, 2003	June 28, 2002
Revenue	$13,714	$ 11,132
Cost of goods sold	5,545	4,033
Gross profit	8,169	7,099
Operating expenses:		
Sales and marketing	3,005	3,041
Research and development	841	625
General and administrative	2,262	1,467
Total operating expenses	6,108	5,133
Income from operations	2,061	1,966
Interest and other income, net	165	86
Income before provision for income taxes	2,226	2,052
Provision for income taxes	957	81
Income from continuing operations	1,269	1,971
Gain (loss) from discontinued operations	26	(581)
Tax provision (benefit) from discontinued operations	11	(23)
Income (loss) from discontinued operations	15	(558)
Net income	$ 1,284	$ 1,413
Income from continuing operations per share:		
Basic	$ 0.09	$ 0.15
Diluted	$ 0.09	$ 0.14
Income (loss) from discontinued operations per share:		
Basic	$ 0.00	$ (0.04)
Diluted	$ 0.00	$ (0.04)
Net income per share:		
Basic	$ 0.09	$ 0.11
Diluted	$ 0.09	$ 0.10

Shares used to compute income per share:		
Basic	13,752	13,344
Diluted	14,338	14,483

See Notes to Condensed Financial Statements

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

	Thirteen Weeks Ended	
	June 27, 2003	**June 28, 2002**
Cash flows from operating activities:		
Net income	$ 1,284	$ 1,413
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	633	622
Change in allowance for losses on accounts receivable	54	(2)
Provision for warranty cost	(21)	(15)
Change in inventory reserve	167	70
Change in allowance for sales returns	(5)	25
Changes in assets and liabilities:		
Accounts receivable	(975)	(287)
Inventories	(174)	(608)
Prepaid expenses and other assets	304	(95)
Accounts payable and accrued expenses	(364)	674
Accrued payroll and benefits	(743)	(942)
Deferred tax assets	743	
Net cash provided by operating activities	903	855
Cash flows from investing activities:		
Sales and maturities of marketable securities	23,954	10,491
Purchases of marketable securities	(20,882)	(11,128)
Purchases of property and equipment	(870)	(641)
Net cash provided by (used in) investing activities	2,202	(1,278)
Cash flows from financing activities:		
Issuance of common stock	741	2,353
Net cash provided by financing activities	741	2,353
Net increase in cash and cash equivalents	3,846	1,930
Cash and cash equivalents at beginning of period	8,747	8,800
Cash and cash equivalents at end of period	$ 12,593	$ 10,730

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

The interim results are not necessarily indicative of the results of operations for the full fiscal year ending March 26, 2004. Certain financial statement items have been reclassified to conform to the current year format.

2. Balance Sheet Data

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

	June 27, 2003	March 28, 2003
Raw materials	$2,432	$2,388
Work-in-process	2,279	1,762
Finished goods	2,102	2,656
	$6,813	$6,806

3. Sale of WellCheck

On December 23, 2002, the Company completed the sale of certain assets and the assignment of certain obligations of its wholly owned subsidiary WellCheck Inc. (WellCheck). The sale was made pursuant to the terms and conditions of a Stock Purchase Agreement (the Agreement) dated December 23, 2002 by and among the Company, WellCheck and ImpactHealth.com, Inc. Under the terms of the Agreement, the Company received a secured promissory note in the aggregate principal amount of $250,000 (the Note) due on the first anniversary of the issuance of the Note, the right to receive an additional $200,000 contingent upon the attainment of certain performance measures and a royalty per participant tested with TEAMS for three years after the date of the agreement. Information presented in the financial statements for prior periods have been adjusted to reflect WellCheck as Discontinued Operations. This change does not have a material impact to the Company s financial statements.

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As a result of the sale, the Company recorded a loss of $4.4 million. The components of the loss are as follows (in thousands):

Net book value of WellCheck assets	$4,695
Less note receivable	(250)
Net expense	$4,445

Revenues and losses of the Company s discontinued operations for the thirteen weeks ended June 27, 2003 and June 28, 2002 (in thousands of dollars) were as follows:

	June 27, 2003	June 28, 2002
Revenues	$ 5	$ 435
Income (loss) before provision for income taxes	21	(581)
Income tax provision (benefit)	11	(23)
Net income (loss)	$ 15	$ (558)

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

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4. Derivative Financial Instruments

At June 27, 2003, the Company had outstanding forward contracts to purchase £1.1 million for approximately $1.7 million. The open contracts mature at various dates through January 15, 2004 and hedge certain forecasted inventory purchases denominated in the British Pounds Sterling. The unrealized gain on the forward contracts at June 27, 2003 was $82,000, all of which is expected to be reclassified to earnings within the next 12 months. There was no gain or loss recorded in the period from hedge ineffectiveness or from forecasted transactions no longer expected to occur.

5. Earnings Per Share

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

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

	Thirteen Weeks Ended	
	June 27, 2003	June 28, 2002
(in thousands, except per share data)		
Income		
Income from continuing operations	$ 1,269	$ 1,971
Income (loss) from discontinued operations	15	(558)
Net Income	$ 1,284	$ 1,413
Shares		
Basic	13,752	13,344
Effect of dilutive securities	586	1,139
Diluted	14,338	14,483
Per share continuing operations:		
Basic	$ 0.09	$ 0.15
Effect of dilutive securities	0.00	(0.01)
Diluted	$ 0.09	$ 0.14
Per share discontinued operations:		
Basic	$ 0.00	$ (0.04)
Effect of dilutive securities	0.00	0.00
Diluted	$ 0.00	(0.04)
Per share net income		
Basic	$ 0.09	$ 0.11
Effect of dilutive securities	0.00	(0.01)
Diluted	$ 0.09	$ 0.10

As of June 27, 2003, options to purchase 920,680 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 June 28, 2002, options to purchase 449,162 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.

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6. Stock-Based Compensation

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

Had compensation costs 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 No. 123, the Company s net income and net income per share would have been as follows:

	Thirteen Weeks ended	
	June 27, 2003	June 28, 2002
(in thousands, except per share data)		
Net income as reported	$1,284	$ 1,413
Deduct total stock-based employee compensation expense determined under fair value based method for all awards	703	495
Net income proforma	$ 581	$ 918
Net Income per share:		
Basic		
As reported	$ 0.09	$ 0.11
Proforma	$ 0.04	$ 0.07
Diluted		
As reported	$ 0.09	$ 0.10
Proforma	$ 0.04	$ 0.06

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

	Thirteen Weeks ended	
	June 27, 2003	June 28, 2002
Risk Free interest rate	1.05%	1.73%
Expected life	7 Years	7 Years
Expected volatility	94.01%	95.13%
Dividend yield	0.0%	0.0%

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7. **Recent Accounting Pronouncements**

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

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

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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 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 the Company in the Commercial Court in Leuven Belgium (No. F8756-02), seeking damages in the amount of approximately 3.5 million for the wrongful termination of an implied distribution agreement with our company for Europe and parts of the Middle East. A hearing was held on April 29, 2003 regarding certain procedural issues. In a judgment rendered on May 27, 2003, the Court referred the complaint to the Constitutional Court before rendering a final decision. The Court asked the Constitutional Court to render an opinion regarding certain constitutional issues related to the trademark infringement arguments the Company raised at the hearing. A hearing in the Constitutional Court was held on July 8, 2003. At this hearing, the Court granted an extension of time for the filing of pleadings. We have until August 31, 2003 to file additional pleadings and a hearing has been scheduled for September 9, 2003. The Company believes these claims are without merit and intends to continue to defend the claims vigorously.

On December 23, 1999, Roche Diagnostics GmbH (Roche) filed suit against the Company and two of its distributors, Health Care Solutions AG and Euromedix N.V./SA, in the Canton Court of the Canton Zug in Zug, Switzerland (No. ES580/1999), seeking a cease and desist order barring the Company from selling HDL assay single-use test cassettes in Switzerland. The complaint alleges that the Company violated a Roche European patent for HDL. On July 11, 2000, the court denied Roche s request for an injunction and ordered it to pay a portion of the Company s legal fees. On May 2, 2002, in response to our motion, the court ruled that it did not have local jurisdiction over the matter and ordered Roche to pay The Company s legal fees. Roche subsequently appealed the May 2, 2002 decision by the Canton Court of the Canton Zug. On October 7, 2002, the Swiss Federal Tribunal referred the matter back to the Canton Court but rejected the jurisdiction aspect of Roche s appeal. At this point in time, no schedule has been set regarding additional court activity. The Company believes the claim is without merit and intends to continue to defend the claim vigorously.

In January 2000, Roche filed suit against the Company and two of its distributors, Micro-Medical GmbH and Euromedix N.V./SA, in the District Court in Dusseldorf, Germany (No. 4aO4/00), seeking a cease and desist order barring us from selling HDL single-use test cassettes in Germany. The complaint alleges the Company violated a Roche German priority patent for

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HDL by selling its single-use test cassette containing a HDL assay in Germany. On December 4, 2001, a hearing was held in Dusseldorf, Germany at which witnesses for Roche and the company testified. On October 29, 2002, the District Court held a hearing on the merits of the case. The court rendered its decision on December 19, 2002, ruling that (i) the Company is not allowed to further distribute HDL test cassettes which correspond to the German Roche patent, (ii) the Company s distributors must destroy HDL products in their possession, (iii) the Company and its distributors are subject to unspecified damages based on all sales which occurred in Germany since December 8, 1995 and (iv) the Company and its distributors must pay the legal fees of the litigation. However, the decision is not enforceable until Roche posts a bond of security in the amount of 2.5 million, approximately $2.7 million. Roche has not yet posted the bond, nor has it notified the Company of an intention to post the bond. On January 10, 2003, the Company appealed this ruling with the Appeal Court in Dusseldorf. The Company believes the claim is without merit and intends to continue to defend the claim vigorously.

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

In September 2000, Roche filed suit against the Company and one of its distributors in the Commercial Court in Vienna, Austria (No. Ei/Ti ROCH 04002), seeking a cease and desist order barring us from distributing HDL assay single-use test cassettes in Austria. The complaint alleges that the Company violated a Roche European patent for HDL. On August 9, 2002, the court ruled in our favor and dismissed the patent infringement claim. There can be no assurance as to whether Roche will take any additional action.

On March 3, 2003, Roche Diagnostics Corporation and Roche Diagnostics GmbH filed suit against the Company in the United States District Court for the Southern District of Indiana (Indianapolis) (No. 03-CV-0303-LJM-WTL), seeking a preliminary and permanent injunction, damages and attorneys fees for patent infringement. The Company was served with the suit on June 30, 2003. The complaint alleges that the Company is violating three Roche U.S. patents for HDL. On July 21, 2003, the Company filed an answer and counter claim with the U.S. District Court for the Southern District of Indiana. The Company believes the claim is without merit and intends to defend the claim vigorously.

Based upon consultation with outside counsel handling the Company s defense in these matters and a discussion of potential results, the Company does not consider a negative litigation outcome to be probable and has not accrued any amounts for potential losses related to these proceedings. Because of uncertainties related to both the amount and range of loss on the pending litigation, management is unable to make a reasonable estimate of the liability that could result from an unfavorable outcome. As additional information becomes available, the Company will assess the potential liability related to its pending litigation. The Company will record accruals for losses if and when the Company determines the negative outcome of such matters to be probable and reasonably estimable. The Company s estimates regarding such losses could differ from actual results. Revisions in the Company s estimates of the potential liability could materially impact the Company s results of operations and financial position. The Company is subject to various

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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 consolidated financial statements.

9. Comprehensive Income

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

(unaudited)	Thirteen Weeks Ended June 27, 2003	Thirteen Weeks Ended June 28, 2002
Net income	$1,284	$ 1,413
Change in unrealized gain on investments, net	(22)	62
Change in future currency contracts	40	4
Total comprehensive income	$1,302	$ 1,479

	Thirteen Weeks Ended June 27, 2003
Balance at the beginning of the year	$ 116
Accruals and charges for warranty for the year	63
Cost of repairs and replacements	(60)
Balance at June 27, 2003	$ 119

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

Certain statements in this Management s Discussion and Analysis of Financial Condition and Results of Operations are forward-looking statements. 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. These statements are only predictions. Actual events or results may differ materially. In evaluating these statements, you should specifically consider various factors, including the risks outlined under Factors Affecting Future Operating Results . These factors may cause our actual results to differ materially from any forward-looking statement.

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

Overview

We develop, manufacture and market products that perform diagnostic testing at sites outside of traditional hospital and clinical laboratories to assist in assessing for risk of heart disease, diabetes and certain liver diseases and in the monitoring of therapy to treat those diseases. Currently, we manufacture and sell the LDX System, which consists of an analyzer, a test cassette, a printer and accessories, and sell the GDX System, which consists of an analyzer, a test cartridge and accessories.

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

In December 2002, we completed the sale of certain assets and the assignment of certain obligations of WellCheck to ImpactHealth. We received a secured promissory note in the aggregate principal amount of $250,000 due on the first anniversary of the issuance of the note, the right to receive an additional $200,000 contingent upon the attainment of certain performance measures and a royalty per participant tested with TEAMS for three years after the date of the agreement. In addition, we entered into a three-year renewable supply agreement with ImpactHealth involving the purchase of the LDX System and single use test cassettes by ImpactHealth on an exclusive basis.

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

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

In addition, legislation to allow Medicare reimbursement for cholesterol was introduced on February 12, 2003 to both the Senate and House of Representatives, and diabetes screening, was introduced on March 11, 2003 in the Senate and May 22, 2003 in the House of Representatives. Both acts have passed in their respective bodies and are now in conference to resolve differences between the two bills. If this legislation is enacted, it may provide further opportunity, starting in calendar 2005, for us to capitalize on the increasing need for testing in both the physician office laboratory and health promotion markets to assess risk for heart disease and diabetes in individuals that we believe could result from passage of such legislation. Further, a major class of cholesterol lowering medications called statins may be approved by the FDA for over the counter sales in the future, which could provide pharmacies with an incentive to conduct testing of patients in the pharmacy as part of a health awareness initiative and provide us with additional opportunities to market our products.

Results of Operations

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

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

	Thirteen Weeks Ended	
	June 27, 2003	June 28, 2002
Revenue	100%	100%
Cost of goods sold	40	36
Gross profit	60	64
Operating expenses		
Sales and marketing	22	27
Research and development	6	6
General and administrative	17	13
Total operating expenses	45	46
Income from operations	15	18
Interest and other income	1	1
Provision for income taxes	7	1
Income from continuing operations	9	18
Loss from discontinued operations	(0)	(5)
Net income	9%	13%

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Thirteen weeks ended June 27, 2003 and June 28, 2002

Revenue. During the thirteen weeks ended June 27, 2003, revenue increased $2.6 million, or 23%, to $13.7 million from $11.1 million for the thirteen weeks ended June 28, 2002. Sales of single-use test cassettes increased $1.1 million, or 12%, from $9.7 million for the thirteen weeks ended June 28, 2002 to $10.8 million for the thirteen weeks ended June 27, 2003. Revenue for our LDX analyzer increased $294,000, or 37%, to $1.1 million for the thirteen weeks ended June 27, 2003 from $800,000 for the thirteen weeks ended June 28, 2002. Revenue for our GDX analyzer and related single use test cartridges was $891,000 for the thirteen weeks ended June 27, 2003, with no comparable sales for the thirteen weeks ended June 28, 2002. Accessories sales increased $252,000, or 38%, to $912,000 for the thirteen weeks ended June 27, 2003 from $660,000 for the thirteen weeks ended June 28, 2002.

During the thirteen weeks ended June 27, 2003, domestic revenue increased $2.0 million, or 21%, to $11.7 million from $9.7 million for the thirteen weeks ended June 28, 2002. The increase in revenue was attributable to the continued adoption by physicians of the ATP III guidelines for treatment of high cholesterol and further penetration into a growing number of CLIA waived laboratories. This resulted in a 43% revenue increase in the physician office laboratory market which increased $2.3 million to $7.7 million during the thirteen weeks ended June 27, 2003, compared to $5.4 million for the thirteen weeks ended June 28, 2002. Most of the increase related to revenue from single-use test cassettes which increased 10% while unit volume increased 14% during the thirteen weeks ended June 27, 2003 compared to the first quarter of fiscal 2002. Additionally, domestic revenue for our GDX analyzer and related single use test cartridges was $731,000 for the thirteen weeks ended June 27, 2003, with no comparable sales for the thirteen weeks ended June 28, 2002.

International revenue increased $560,000, or 39%, to $2.0 million for the thirteen weeks ended June 27, 2003 from $1.4 million for the thirteen weeks ended June 28, 2002. The increase related primarily to the launch by AstraZeneca PLC of the statin Crestor in the United Kingdom and Mexico, and the preparation for its launch in Germany, Spain and Italy. Additionally, AstraZeneca s competitors are increasing promotional spending to counter the impact of Crestor s launch. The increase related primarily to the sale of single-use test cassettes which increased $283,000, or 28%, to $1.3 million for the thirteen weeks ended June 27, 2003 compared to $1.0 million for the thirteen weeks ended June 28, 2002. Additionally, international revenue for our GDX and related products was $159,000 for the thirteen weeks ended June 27, 2003, with no comparable sales for the thirteen weeks ended June 28, 2002.

Cost of Goods Sold. Cost of goods sold increased $1.5 million, or 37%, to $5.5 million for the thirteen weeks ended June 27, 2003 from $4.0 million for the thirteen weeks ended June 28, 2002. Gross margins were 60% and 64% for the thirteen weeks ended June 27, 2003 and June 28, 2002, respectively. Cost of goods sold includes direct labor, direct material, overhead and royalties. The increase in cost of goods sold as a percentage of sales was primarily related to a 4% decrease in average sale price for single-use test cassette and the introduction of the GDX analyzer and test cartridges, which have a lower margin than the products we manufacture. Factory spending increased $377,000, or 11%, and cassette unit production increased 13% for the thirteen weeks ended June 27, 2003, from the thirteen weeks ended June 28, 2002. Spending increases related primarily to scrap, facility related costs for the larger production area which we began occupying in September 2002, and production labor and related costs.

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

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expenses decreased $36,000, or 1%, to $3.0 million for the thirteen weeks ended June 27, 2003 from $3.0 million for the thirteen weeks ended June 28, 2002. Product marketing expenses decreased $110,000 due mainly to lower trade show expenses, and compensation decreased $80,000 due to a lower commission accrual rate, offset by an $113,000 increase in travel expenses. Over the balance of the fiscal year, we expect sales and marketing expenses to increase as our involvement in trade shows and distributor relations activity increases.

Research and Development Expenses. Research and development expenses include salaries, bonuses, expenses for professional consulting services, supplies and depreciation of capital equipment. Research and development expenses increased $216,000, or 35%, to $841,000, for the thirteen weeks ended June 27, 2003 from $625,000 for the thirteen weeks ended June 28, 2002. Research and development expenses as a percentage of total revenue remained constant at 6% for both the thirteen weeks ended June 27, 2003 and the thirteen weeks ended June 28, 2002. The increase was mainly attributable to a $67,000 increase for wage and related costs, $61,000 for material used in new product development and $49,000 for outside professional services. All of these increases related to accelerated activities in new product development.

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 $795,000, or 54%, to $2.3 million for the thirteen weeks ended June 27, 2003 from $1.5 million for the thirteen weeks ended June 28, 2002. As a percentage of total revenue, general and administrative expenses increased to 17% for the thirteen weeks ended June 27, 2003 from 13% for the thirteen weeks ended June 28, 2002. The increase related to $284,000 in higher fees for outside professional services including legal and accounting services, and an $182,000 increase in insurance premiums for directors and officers. The increase was also attributable to higher expenditures for head count related expenses including benefits, training and travel. We expect legal expenses to increase over the balance of the fiscal year relating to the suit filed by Roche on March 3, 2003.

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 increased $79,000, or 92%, to $165,000 for the thirteen weeks ended June 27, 2003 from $86,000 for the thirteen weeks ended June 28, 2002. The increase was due to a 9% increase in the amount invested in securities and the gain on sale of certain securities.

Income Taxes. For the thirteen weeks ended June 27, 2003, the provision for income taxes increased $876,000, or 1,081%, to $957,000 compared to $81,000 for the thirteen weeks ended June 28, 2002, which was at a significantly lower effective tax rate.

Based on our recent positive operating results, in the fourth quarter of fiscal 2003 we determined that it was increasingly likely that we would be able to realize a portion of our net operating loss carryforwards in future periods thereby reducing taxes to be paid in those periods, A valuation allowance of $4.2 million for deferred tax assets was released for the amount of net operating loss carry forwards expected to be utilized in fiscal 2004 and fiscal 2005. Beginning with the thirteen weeks ended June 27, 2003, we recognized deferred tax expense for the value of net operating losses utilized based on an estimated effective tax rate for the year of 43%. Based on future results, we may recognize additional deferred tax benefits to be realized in future periods. Since we have significant federal net operating losses and both federal and California tax credit carryforwards, the provision for income taxes for the thirteen weeks ended June 28, 2002 primarily represents the estimated alternative minimum tax.

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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 related to the operations of the WellCheck segment, which was sold on December 23, 2002. The gain of $26,000 in the thirteen weeks ended June 27, 2003 was primarily attributable to expenses related to adjustments to the previously recognized loss. During the thirteen weeks ended June 28, 2002, the net loss from operations of $558,000 related to testing operations for the full fiscal quarter.

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

Liquidity and Capital Resources

We have financed our operations primarily through the sale of equity securities and from positive cash flows from operations. From inception to June 27, 2003, we have raised $83.0 million in net proceeds from equity financings. As of June 27, 2003, we had $26.9 million of cash, cash equivalents and short and long-term marketable securities. In addition to these amounts, we have available a $4.0 million revolving bank line of credit with Wells Fargo Bank, N.A. While the line of credit is in effect, we are required to deposit assets with a collective value, as defined in the line of credit agreement, equivalent to no less than 100% of the outstanding principal balance. Amounts outstanding under the line of credit bear interest at either our choice of 0.5% below the bank s prime rate or 1.75% above the LIBOR rate, depending on the payment schedule. The line of credit agreement expires on September 1, 2004. As of June 27, 2003, we had no borrowings outstanding under this line of credit.

Cash, cash equivalents and total investments were $26.9 million at June 27, 2003, an increase of $792,000, or 3%, from March 28, 2003. Cash provided by operations during the thirteen weeks ended June 27, 2003 was $903,000, which was $48,000, or 6%, higher than the thirteen weeks ended June 28, 2002. The improvement related mainly to the increase in pre-tax income. During the three months ended June 27, 2003 accounts receivable increased $975,000 due to a significant increase in sales during the last month of the quarter. Additionally, accounts payable and accrued expenses decreased by $364,000 due to payment timing of trade payables.

Additions to plant and equipment were $870,000 and $641,000 for the first thirteen weeks of fiscal 2003 and fiscal 2002, respectively. The capital spending for both the current and prior year was related to tenant improvements, expansion of our manufacturing capacity, and development and expansion of our information technology systems. As of June 27, 2003, we had committed to approximately $300,000 of this amount to complete the expansion of our Hayward facility.

Sales of common stock through the employee stock option program and employee stock purchase program were $741,000 for the thirteen weeks ended June 27, 2003, a decrease of $1.6 million, or 69%, from the thirteen weeks ended June 28, 2002. The decline related to decreased exercises of stock options due to a decrease in the value of shares of our common stock on the open market.

Based on current plans and business conditions, we believe that our existing cash, cash equivalents, marketable securities, cash flows anticipated to be generated by future operations and available bank borrowings under our existing line of credit will be sufficient to meet our anticipated operating

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requirements for at least the next 12 months. We expect legal expenses to increase over the balance of the fiscal year relating to the defence of lawsuits. We believe our existing cash, cash equivalent, and marketable securities will be an adequate source of funds for our legal defense. We cannot be certain, however, that our underlying assumed levels of revenues and expenses will be accurate. We may be required to expend greater than anticipated funds if unforeseen difficulties arise relating to modifying or expanding facilities, obtaining necessary product regulatory approvals, scaling up manufacturing for new tests or other matters.

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

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

Critical Accounting Policies

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

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

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Recent Accounting Pronouncements

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

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

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Factors Affecting Future Operating Results

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

Our revenue and operating results have varied significantly from quarter to quarter in the past and may continue to fluctuate in the future. As of June 27, 2003, we had an accumulated deficit of $36.3 million. Our first profitable quarter was the third quarter of fiscal 1998, and our first profitable year was fiscal 1998. We recorded a net loss of $2.6 million for fiscal 2001, a net profit of $5.6 million for fiscal 2002 and a net profit of $4.9 million for fiscal 2003. The following are among the factors that could cause our revenue, operating results and margins to fluctuate significantly from quarter to quarter:

the timing and level of market acceptance of the LDX System and the GDX System;

variations in manufacturing efficiencies;

the timing of the introduction, availability and market acceptance of new tests and products;

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

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

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changes in demand for our products based on changes in third party reimbursement, competition, changes in government regulation and other factors;

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

product pricing and discounts;

additional cost of expanded leased facilities;

promotional program spending by European pharmaceutical companies; variations in the mix of products sold; and

general economic conditions.

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

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

Our success depends in part on our ability to develop and maintain the proprietary aspects of our technology and operate without infringing the proprietary rights of others. We have nine United States patents 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 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

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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 information concerning current legal proceedings see Legal Proceedings in this Quarterly Report on Form 10-Q.

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

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

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

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

With the advent of the internet, new avenues have been created for the dissemination of information. We do not have control over the information that is distributed and discussed on electronic bulletin boards and investment chat rooms. The motives of the people or organizations that distribute such information may not be in our best interest or in the interest of our shareholders. This, in addition to other forms of investment information, including newsletters and research publications, could result in a sharp 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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We depend on technology that we license from others, which may not be available to us in the future and would prevent us from introducing new products and harm our business

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

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 medical products and services;
- healthcare providers are moving toward a managed care system in which they provide comprehensive healthcare for a fixed cost per patient and authorize 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.

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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 in the future and for market forces to demand reduced costs. We cannot predict what impact the adoption of any federal or state healthcare reform measures, future private sector reform or market forces may have on our business. Any changes in the healthcare system could potentially have extremely negative effects on our business.

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

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

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

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

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date relative to the size of the available market. Factors that could prevent broad market acceptance of the LDX System and the GDX System include:

- low levels of awareness of the availability of our technology in both the physician and other customer groups;
- the availability and pricing of other testing alternatives;
- many managed care organizations have contracts with laboratories, which require participating or employed physicians to send patient specimens to contracted laboratories;
- physicians are under growing pressure by Medicare and other third party payors to limit their testing to medically necessary tests; and
- a decrease in the amount of reimbursement for performing tests on the LDX System and the GDX System.

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

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

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

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

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

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new tests must obtain proper regulatory approvals to be marketed.

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

We face risks from failures in our manufacturing processes

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

raw materials variations or impurities;

manufacturing process variances and impurities; and

decreased manufacturing equipment performance.

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

as our production levels have increased, we have been required to use our machinery more hours per day and the down time resulting from equipment failure has increased;

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

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

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

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

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

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

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

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

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

unexpected changes in regulatory requirements;

the impact of recessions in economies outside the United States;

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

less effective protection of intellectual property rights in some countries;

changes in tariffs and other trade protection measures;

difficulties in managing international operations; and

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

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

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

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

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

To increase revenue and achieve sustained profitability, we will have to maintain and expand our existing distribution relationships and develop new distribution relationships. We are dependent 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, those distributors may de-emphasize or decline to carry our products. If we are unable to maintain successful relationships with distributors or to expand our distribution channels, our business will suffer.

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

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

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

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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.

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

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

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

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

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

In addition, United States income tax law imposes limitations on the ability of corporations to use net operating loss carryforwards if the corporation experiences a more than 50% change in ownership during any three-year period. We cannot assure you that we will not take actions, such as the issuance of

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additional stock, that would cause an ownership change to occur. Accordingly, we may be limited to the amount we can use in any given year, so even if we have substantial net income, we may not be able to use our net operating loss carryforwards before they expire. In addition, the net operating loss carryforwards are subject to examination by the Internal Revenue Service, or IRS, and are thus subject to adjustment or disallowance resulting from any such IRS examination.

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

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

Our manufacturing processes and, in certain instances, those of our contract manufacturers, are subject to stringent federal, state and local regulations governing the use, generation, manufacture, storage, handling and disposal of certain materials and wastes. Failure to comply with present or future regulations could result in many things, including warning letters, fines, injunctions, civil penalties, 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 the maintenance of a quality system consistent with Food and Drug Administration regulations;
- ISO9001/EN46001 requirements, which is an industry standard for maintaining and assuring conformance to quality standards; and
- other foreign regulations and state and local health, safety and environmental regulations, which include testing, control and documentation requirements.

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

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

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

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

We continue to evaluate strategic opportunities available to us and we may pursue product, technology or business acquisitions. These acquisitions could be very costly, could result in dilution to existing investors and could result in integration problems that harm our business as a whole. Any

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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.

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

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

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

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

We currently maintain product liability insurance and professional liability insurance for claims relating to the past performance of testing services, but there can be no assurance that the coverage

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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 hurt 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 antitakeover plan. The issuance of preferred stock under certain circumstances could have the effect of delaying or preventing an acquisition of our company or otherwise adversely affecting the rights of the holders of our stock. The poison pill may have the effect of rendering more difficult or discouraging an acquisition of our company which is deemed undesirable by our board of directors. The poison pill may cause substantial dilution to a person or group attempting to acquire us on terms or in a manner not approved by our board of directors, except pursuant to an offer conditioned on the negation, purchase or redemption of the rights issued under the poison pill.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Quantitative Disclosures

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

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

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

We enter into forward exchange contracts to manage foreign currency exposures arising from inventory purchases and accounts payable denominated in foreign currencies. Our policy is to hedge 100% of all committed purchase contracts and a lesser percentage for forecasted purchases. At June 27, 2003, we had outstanding forward contracts to purchase £1.1 million for approximately $1.7 million. The open contracts mature at various dates through January 15, 2004 and hedge certain forecasted inventory purchases denominated in the British Pound Sterling. The unrealized gain on the forward contracts at June 27, 2003 was $82,000, all of which is expected to be reclassified to earnings within the next 12 months. There was no gain or loss recorded in the period from hedge ineffectiveness or from forecasted transactions no longer expected to occur. We do not enter into foreign exchange forward contracts for trading purposes. We do not expect gains or losses on these contracts to have a material impact on our financial results.

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

	Fiscal Year					
	2004	2005	2006	2007	Total	Fair Value
	(in thousands)					
Cash, cash equivalents	$12,593	$	$	$	$12,593	$12,593
Short-term marketable securities	$ 1,587	$ 849	$	$	$ 2,436	$ 2,436
Weighted average interest rate	1.49%	3.98%				
Long-term marketable securities	$	$7,870	$3,866	$ 108	$11,844	$11,844
Weighted average interest rate		2.38%	2.96%	4.27%		

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

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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

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure based closely on the definition of disclosure controls and procedures in Rule 13a-14(c). In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Within 90 days prior to the date of this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective.

There have been no significant changes in our internal controls or in other factors that could significantly affect the internal controls subsequent to the date we completed our evaluation.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On August 2, 2002, N.V. Euromedix (Euromedix) filed suit against us in the Commercial Court in Leuven Belgium (No. F5700-02), seeking damages for the wrongful termination of an implied distribution agreement with our company for Europe and parts of the Middle East. On November 7, 2002, the court dismissed the suit. On December 31, 2002, Euromedix filed suit against us in the Commercial Court in Leuven Belgium (No. F8756-02), seeking damages in the amount of approximately 3.5 million for the wrongful termination of an implied distribution agreement with our company for Europe and parts of the Middle East. A hearing was held on April 29, 2003 regarding certain procedural issues. In a judgment rendered on May 27, 2003, the Court referred the complaint to the Constitutional Court before rendering a final decision. The Court asked the Constitutional Court to render an opinion regarding certain constitutional issues related to the trademark infringement arguments we raised at the hearing. A hearing in the Constitutional Court was held on July 8, 2003. At this hearing, the Court granted an extension of time for the filings of pleadings. We have until August 31, 2003 to file additional pleadings and a hearing has been scheduled for September 9, 2003. We believe these claims are without merit and intend to continue to defend the claims vigorously.

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On December 23, 1999, Roche Diagnostics GmbH (Roche) filed suit against us and two of our distributors, Health Care Solutions AG and Euromedix N.V./SA, in the Canton Court of the Canton Zug in Zug, Switzerland (No. ES580/1999), seeking a cease and desist order barring us from selling HDL assay single-use test cassettes in Switzerland. The complaint alleges that we violated a Roche European patent for HDL. On July 11, 2000, the court denied Roche s request for an injunction and ordered it to pay a portion of our legal fees. On May 2, 2002, in response to our motion, the court ruled that it did not have local jurisdiction over the matter and ordered Roche to pay our legal fees. Roche subsequently appealed the May 2, 2002 decision by the Canton Court of the Canton Zug. On October 7, 2002, the Swiss Federal Tribunal referred the matter back to the Canton Court but rejected the jurisdiction aspect of Roche s appeal. At this point in time, no schedule has been set regarding additional court activity. We believe the claim is without merit and intend to continue to defend the claim vigorously.

In January 2000, Roche filed suit against us and two of our distributors, Micro-Medical GmbH and Euromedix N.V./SA, in the District Court in Dusseldorf, Germany (No. 4aO4/00), seeking a cease and desist order barring us from selling HDL single-use test cassettes in Germany. The complaint alleges we violated a Roche German priority patent for HDL by selling our single-use test cassette containing a HDL assay in Germany. On December 4, 2001, a hearing was held in Dusseldorf, Germany at which witnesses for Roche and our company testified. On October 29, 2002, the District Court held a hearing on the merits of the case. The court rendered its decision on December 19, 2002, ruling that (i) we are not allowed to further distribute HDL test cassettes which correspond to the German Roche patent, (ii) our distributors must destroy HDL products in their possession, (iii) we and our distributors are subject to unspecified damages based on all sales which occurred in Germany since December 8, 1995 and (iv) we and our distributors must pay the legal fees of the litigation. However, the decision is not enforceable until Roche posts a bond of security in the amount of 2.5 million, approximately $2.7 million. Roche has not yet posted the bond, nor has it notified the Company of an intention to post the bond. On January 10, 2003, we appealed this ruling with the Appeal Court in Dusseldorf. We believe the claim is without merit and intend to continue to defend the claim vigorously.

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

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

On March 3, 2003, Roche Diagnostics Corporation and Roche Diagnostics GmbH filed suit against us in the United States District Court for the Southern District of Indiana (Indianapolis) (No. 03-CV-0303-LJM-WTL), seeking a preliminary and permanent injunction, damages and attorneys fees for patent infringement. We were served with the suit on June 30, 2003. The complaint alleges that we are violating three Roche U.S. patents for HDL. On July 21, 2003, we filed an answer and counter claim with the U.S. District Court for the Southern District of Indiana. We believe the claim is without merit and intend to defend the claim vigorously.

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Based upon consultation with outside counsel handling our defense in these matters and a discussion of potential results, we do not consider a negative litigation outcome to be probable and have not accrued any amounts for potential losses related to these proceedings. Because of uncertainties related to both the amount and range of loss on the pending litigation, management is unable to make a reasonable estimate of the liability that could result from an unfavorable outcome. As additional information becomes available, we will assess the potential liability related to our pending litigation. We will record accruals for losses if and when we determine the negative outcome of such matters to be probable and reasonably estimable. Our estimates regarding such losses could differ from actual results. Revisions in our estimates of the potential liability could materially impact our results of operations and financial position.

ITEM 5. OTHER INFORMATION.

In accordance with Section 10A(i)(2) of the Securities Exchange Act of 1934, as promulgated by Section 202 of the Sarbanes-Oxley Act of 2002 (the Act), we are required to disclose the non-audit services approved by our Audit Committee to be performed by PricewaterhouseCoopers LLP, our external auditor. Non-audit services are defined in the Act as services other than those provided in connection with an audit or review of the financial statements of a company. The Audit Committee has approved the engagement of PricewaterhouseCoopers LLP to provide services in connection with the preparation of state tax returns.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K.

(a) Exhibits.

10.17.9 Revolving Line of Credit Note effective July 1, 2003 by and between Wells Fargo Bank and Registrant.

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

(b) Reports on Form 8-K.

We filed a Report on Form 8-K (File No. 000-20198) with the Securities and Exchange Commission on April 23, 2003, to furnish our press release regarding our financial results for the fiscal year ended March 28, 2003.

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SIGNATURES

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

CHOLESTECH CORPORATION

Date: August 7, 2003

/s/ Warren E. Pinckert II

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

Date: August 7, 2003

/s/ William W. Burke

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

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I, Warren E. Pinckert II, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Cholestech Corporation;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

   a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

   b) evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and

   c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant s other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

6. The registrant s other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: August 7, 2003

/s/ Warren E. Pinckert II

Warren E. Pinckert II
President and Chief Executive Officer

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I, William W. Burke, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Cholestech Corporation;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

   a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

   b) evaluated the effectiveness of the registrant s disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date); and

   c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant s other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant s auditors and the audit committee of registrant s board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant s ability to record, process, summarize and report financial data and have identified for the registrant s auditors any material weaknesses in internal controls; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant s internal controls; and

6. The registrant s other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: August 7, 2003

/s/ William W. Burke

William W. Burke
Vice President of Finance and
Chief Financial Officer

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INDEX TO EXHIBITS

Exhibit No.	Description
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