CHOLESTECH CORPORATION
Form 10-Q
August 09, 2006

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-Q

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

For the quarterly period ended June 30, 2006

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 000-20198

CHOLESTECH CORPORATION

(Exact name of registrant as specified in its charter)

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o Accelerated filer þ Non-accelerated filer o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No þ

As of July 31, 2006, 14,988,875 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)
(unaudited)

	June 30, 2006	March 31, 2006(1)
Assets		
Current assets:		
Cash and cash equivalents	$ 6,473	$ 7,161
Marketable securities	30,859	21,071
Accounts receivable, net	4,734	5,129
Inventories, net	8,005	7,525
Prepaid expenses and other assets	1,750	2,199
Deferred tax assets	1,524	775
Total current assets	53,345	43,860
Property and equipment, net	7,305	7,820
Intangible assets, net	472	492
Long-term marketable securities	9,127	14,444
Long-term deferred tax assets	12,464	13,736
Other long-term assets	446	350
Total assets	$ 83,159	$ 80,702
Liabilities and Shareholders Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,165	$ 2,785
Accrued payroll and benefits	2,404	3,544
Other liabilities	209	241
Total current liabilities	5,778	6,570
Contingencies (note 8)		
Shareholders equity:		
Common stock, no par value; 25,000,000 shares authorized; 14,980,005 and 14,868,825 shares issued and outstanding at June 30, 2006 and March 31, 2006, respectively	95,894	94,015
Accumulated other comprehensive loss	(138)	(125)
Deferred compensation	(773)	(660)
Accumulated deficit	(17,602)	(19,098)

Total shareholders equity		77,381		74,132
Total liabilities and shareholders equity	$	83,159	$	80,702

(1) The information in this column was derived from the Company s audited financial statements as of the fiscal year ended March 31, 2006.

See Notes to Unaudited Condensed Financial Statements

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

	Thirteen Weeks Ended	
	June 30, 2006	June 24, 2005
Revenue	$ 16,784	$ 15,065
Cost of revenue	5,599	5,472
Gross profit	11,185	9,593
Operating expenses:		
Sales and marketing	3,888	3,312
Research and development	1,383	1,067
General and administrative	3,780	2,755
Total operating expenses	9,051	7,134
Income from operations	2,134	2,459
Interest and other income, net	468	133
Income before provision for income taxes	2,602	2,592
Provision for income taxes	1,106	1,000
Net income	$ 1,496	1,592
Net income per share:		
Basic	$ 0.10	$ 0.11
Diluted	$ 0.10	$ 0.11
Shares used to compute income per share:		
Basic	14,824	14,618
Diluted	15,193	14,913

See Notes to Unaudited Condensed Financial Statements

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

	Thirteen Weeks Ended	
	June 30, 2006	June 24, 2005
Cash flows from operating activities:		
Net income	$ 1,496	$ 1,592
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	749	686
Stock-based compensation	776	25
Tax benefits from equity based compensation	179	
Excess tax benefits from equity based compensation plans	(128)	
Change in allowance for doubtful accounts	(2)	(44)
Change in inventory reserve	(17)	(115)
Change in deferred tax asset	523	972
Changes in assets and liabilities:		
Accounts receivable	397	567
Inventories	(463)	(247)
Prepaid expenses and other assets	449	327
Other long-term assets	(96)	(87)
Accounts payable and accrued expenses	380	(914)
Accrued payroll and benefits	(1,140)	(1,005)
Other liabilities	(32)	(34)
Net cash provided by operating activities	3,071	1,723
Cash flows from investing activities:		
Sales and maturities of marketable securities	14,272	6,710
Purchases of marketable securities	(18,756)	(6,830)
Purchases of property and equipment	(214)	(877)
Net cash used in investing activities	(4,698)	(997)
Cash flows from financing activities:		
Issuance of common stock	811	301
Excess tax benefits from equity based compensation plans	128	
Net cash provided by financing activities	939	301
Net increase (decrease) in cash and cash equivalents	(688)	1,027
Cash and cash equivalents at beginning of period	7,161	4,304

Cash and cash equivalents at end of period	$ 6,473	$ 5,331

See Notes to Unaudited Condensed Financial Statements

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NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

1. Basis of Presentation

The interim unaudited financial information of Cholestech Corporation (the Company) is prepared in conformity with accounting principles generally accepted in the United States of America. The financial information included herein has been prepared by management and should be read in conjunction with the audited financial statements contained in the Annual Report on Form 10-K for the fiscal year ended March 31, 2006. The information furnished includes all adjustments and accruals consisting only of normal recurring accrual adjustments that are, in the opinion of management, necessary for a fair presentation of results for the interim periods. Certain information or footnote disclosure normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America has been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission.

The interim results are not necessarily indicative of the results of operations for the full fiscal year ending March 30, 2007, or any other future interim period.

2. Summary of Significant Accounting Policies

The Company s significant accounting policies are disclosed in the Company s Annual Report on Form 10-K for the year ended March 31, 2006 filed with the Securities and Exchange Commission. The Company s significant accounting policies reflect the adoption of the provisions of Statement of Financial Accounting Standards (SFAS) No. 123 (revised 2004), Share-Based Payment (SFAS 123(R)); and have otherwise not materially changed during the thirteen weeks ended June 30, 2006.

Beginning April 1, 2006, the Company began accounting for stock options and shares issued under its employee stock purchase plan (ESPP) under SFAS 123(R), which requires the recognition of the fair value of equity based compensation. The fair value of stock options was estimated using a Black-Scholes option valuation model. This model requires the Company to make subjective assumptions in implementing SFAS 123(R), including expected stock price volatility, estimated life and estimated forfeitures of each award. The fair value of equity-based awards is amortized over the vesting period of the award, and the Company has elected to use the straight-line method. The Company makes quarterly assessments of the adequacy of the tax credit pool to determine if there are any deficiencies which require recognition in the condensed statement of operations.

The Company has elected to adopt the alternative transition method provided under the provisions of Financial Accounting Standards Board (FASB) Staff Position No. FAS 123(R) 3 Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards. The alternative transition method includes simplified methods to establish the beginning balance of the additional paid-in capital pool (APIC pool) related to the tax effects of employee stock-based compensation, and to determine the subsequent impact on the APIC pool and statements of cash flows of the tax effects of employee stock-based compensation awards that are outstanding upon adoption of SFAS 123(R).

3. Recent Accounting Pronouncements

In July 2006, the FASB issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement No. 109 (FIN 48), which clarifies the accounting for uncertainty in income tax positions. This Interpretation requires that the Company recognize in its financial statements the impact of a tax position if that position is more likely than not of being sustained on audit, based on the technical merits of the position. The provisions of FIN 48 are effective for the Company on March 31, 2007, with the cumulative effect of the change in accounting principle, if any, recorded as an adjustment to opening retained earnings. The Company is currently evaluating the impact of adopting FIN 48 on its financial position, cash flows, and results of operations.

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4. Balance Sheet Data

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

	June 30, 2006	March 31, 2006
Raw materials	$ 2,333	$ 2,662
Work-in-process	2,051	2,110
Finished goods	3,621	2,753
	$ 8,005	$ 7,525

5. Reclassifications

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

6. Net Income Per Share

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

	Thirteen Weeks Ended	
(in thousands, except per share data)	June 30, 2006	June 24, 2005
Net income	$ 1,496	$ 1,592
Shares		
Basic	14,824	14,618
Effect of dilutive securities	369	295
Diluted	15,193	14,913
Per share net income		
Basic	$ 0.10	$ 0.11
Effect of dilutive securities	0.00	0.00
Diluted	$ 0.10	$ 0.11

As of June 30, 2006, options to purchase 204,270 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 24, 2005, options to purchase 704,163 shares of common stock were considered anti-dilutive because the respective exercise prices were greater than the average fair market value of the common stock.

7. Stock-Based Compensation

Effective April 1, 2006, the Company adopted SFAS No. 123(R) using the modified prospective transition method. Under this new standard, the Company s estimate of compensation expense requires a number of complex and subjective assumptions, including the price volatility of Cholestech s common stock, employee exercise patterns (expected life of the options), future

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forfeitures and related tax effects. Prior to the adoption of SFAS 123(R), the Company accounted for stock option grants to employees using the intrinsic value method, in accordance with Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees (APB 25) and accordingly, recognized no compensation expense for stock option grants to employees.

Under the modified prospective approach, SFAS 123(R) applies to new awards and to awards that were outstanding on April 1, 2006 that are subsequently modified, repurchased or cancelled. Under the modified prospective approach, compensation cost recognized for the thirteen weeks ended June 30, 2006 includes compensation cost for all stock-based payments granted prior to, but not yet vested as of, April 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of SFAS 123, and compensation cost for all stock-based payments granted subsequent to April 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123(R). Prior periods were not restated to reflect the impact of adopting the new standard.

Prior to April 1, 2006, the Company accounted for its stock-based employee compensation arrangements using the intrinsic value method of accounting. Compensation expense was based on the difference, if any, on the date of the 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, were realized ratably over the vesting period. The following table illustrates the effect on the Company s net income and net income per share had compensation expense for stock-based compensation been determined in accordance with SFAS 123 for the thirteen weeks ended June 24, 2005 (in thousands, except per share amounts):

(in thousands, except per share data)	Thirteen Weeks Ended June 24, 2005
Net income as reported	$ 1,592
Add: Stock-based employee compensation expense included in reported net income, net of tax	15
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of tax	(683)
Pro forma net income	$ 924
Net income per share:	
Basic	
As reported	$ 0.11
Pro forma	$ 0.06
Diluted	
As reported	$ 0.11
Pro forma	$ 0.06

The fair value of each stock option is estimated on the date of the grant using the Black-Scholes valuation model, with the following weighted-average assumptions used for grants during the applicable periods:

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	Thirteen Weeks Ended	
	June 30, 2006	June 24, 2005
Risk free interest rate	5.08%	3.73%
Expected life	4.6 Years	4.5 Years
Expected volatility	58.5%	65.0%
Dividend yield	0.0%	0.0%
Weighted-average grant-date fair value	$7.43	$5.09

The expected term of stock options represents the weighted-average period the stock options are expected to remain outstanding. The expected term was developed based on observed and expected time to post-vesting exercise, cancellation or forfeiture of an option. Expected volatility was derived exclusively from an analysis of the Company s historical stock prices. The risk-free interest rate is based on the implied yield currently available on U.S. Treasury zero-coupon issues with a remaining term equal to the expected term of the option. The expected dividend assumption is based on the Company s history and expectation of foreseeable dividend payouts.

The Company recognizes stock-based compensation costs for grants made after April 1, 2006 on a straight-line basis over the requisite service period of the award, which is generally the option vesting term. These costs should reflect awards ultimately expected to vest, and have therefore been reduced for estimated forfeitures. The Company has used a 4.1% forfeiture rate in its calculation of stock-based compensation expense based on historical experience over the term. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Prior to April 1, 2006, the Company accounted for forfeitures as they occurred.

Stock Incentive Program

The following table summarizes stock option activity under the 1997 program, 1999 program, and 2000 program for the thirteen weeks ended June 30, 2006:

	Outstanding Options	**Weighted Average Exercise Price Per Share**
Balance, March 31, 2006	2,228,549	$ 10.12
Granted	34,500	14.04
Exercised	(90,264)	7.87
Canceled	(25,332)	16.14
Balance, June 30, 2006	2,147,453	$ 10.20

The following table summarizes information about stock options outstanding as of June 30, 2006:

	Options Outstanding			**Options Exercisable**	
Range of Exercise Prices	**Number**	**Weighted Avg. Contractual Life (years)**	**Weighted Avg. Exercise Price**	**Number**	**Weighted Avg. Exercise Price**
$4.28 - $6.97	94,046	7.5	$ 6.66	46,491	$ 6.35
$6.98 - $8.29	545,612	6.1	7.77	479,255	7.76
$8.30 - $10.20	809,357	8.0	9.35	394,206	9.15
$10.21 - $12.50	468,388	8.2	11.85	186,961	11.86
$12.51 - $17.85	230,050	6.4	17.07	195,550	17.61

2,147,453	7.4	$	10.20	1,302,463	$	10.20

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At June 30, 2006 the aggregate intrinsic value of options outstanding was $5.4 million and the aggregate intrinsic value of outstanding options exercisable was $3.3 million.

Employee stock purchase plan

In August 2002, the shareholders approved the 2002 Employee Stock Purchase Plan (the ESPP) which reserved 400,000 shares of common stock to be issued in accordance with the Internal Revenue Code under such terms as approved by the board of directors. Under the terms of the ESPP, employees can choose quarterly to have up to 15% of their compensation withheld to purchase shares of common stock. Starting May 1, 2005 the Company amended the ESPP such that employees can purchase shares of common stock at a price per share that is 85% of the closing price of the common stock on the NASDAQ National Market on the last trading day of the quarterly purchase period. Prior to May 1, 2005, each offering period was for two years and consisted of four six-month purchase periods. The price of the common stock purchased was 85% of the lesser of the fair market value of the common stock on the first day of the applicable offering period or the last day of each purchase period. During the thirteen weeks ended June 30, 2006 and June 24, 2005 the Company sold 9,241 and 0 shares, respectively, of common stock to employees under the ESPP.

Restricted stock

The Company grants restricted stock to key employees as a means of retaining and rewarding them for long-term performance and to increase their ownership in the Company. Shares awarded under the plan entitle the shareholder to all rights of common stock ownership except that the shares may not be sold, transferred, pledged, exchanged or otherwise disposed of during the restriction period. The restriction period is determined by a committee, appointed by the board of directors, and may not exceed ten years.

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A summary of the changes in restricted stock outstanding under the Company s equity compensation plans during the thirteen weeks ending June 30, 2006 is set forth below:

	Shares	Weighted Avg. Grant Date Fair Value	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Restricted stock at March 31, 2006	65,436	$ 10.84	3.8	$ 831,000
Granted	11,675	14.04	3.9	148,000
Vested	(1,837)	9.26		(23,000)
Forfeited				
Restricted stock at June 30, 2006	75,274	$ 11.38	3.4	$ 956,000

As of June 30, 2006, the Company had $773,000 of deferred compensation related to restricted stock grants, which will be recognized over the weighted average period of 3.4 years.

Shareholder rights plan

In January 1997, the board of directors approved a shareholder rights plan under which shareholders of record on March 31, 1997 received a right to purchase (the Right) one-thousandth of a share of Series A participating preferred stock at an exercise price of $44.00, subject to adjustment. The Rights will separate from the common stock and Rights certificates will be issued and will become exercisable on the earlier of: (i) ten days (or such later date as may be determined by a majority of the board of directors) following a public announcement that a person or group of affiliated or associated persons has acquired, or obtained the right to acquire, beneficial ownership of 15% or more of the Company s outstanding common stock or (ii) ten business days following the commencement of, or announcement of an intention to make, a tender offer or exchange offer, the consummation of which would result in the beneficial ownership by a person or group of 15% or more of the Company s outstanding common stock. The Rights expire on the earlier of (i) January 22, 2007 or (ii) the redemption or exchange of the Rights.

Stock option acceleration

On March 23, 2005, the board of directors of the Company, acting upon the recommendation of the compensation committee of the board of directors, approved an acceleration of vesting for all outstanding unvested stock options with a per share exercise price equal to or greater than $12.06 (the Acceleration). These options had exercise prices in excess of the current market value of the common stock on March 23, 2005, therefore, no expense was recognized on the Acceleration. The options to purchase 93,337 shares of the Company s common stock at exercise prices ranging from $12.06 to $17.85 became immediately exercisable as of March 23, 2005.

8. Contingencies

On August 2, 2002, N.V. Euromedix (Euromedix) filed suit against the Company in the Commercial Court in Leuven, Belgium (No. F5700-02), seeking damages for the wrongful termination of an implied distribution agreement with the Company for Europe and parts of the Middle East. On November 7, 2002, the court dismissed the suit. On December 31, 2002, Euromedix filed another suit against the Company in the Commercial Court in Leuven, Belgium

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(No. B/02/00044), seeking damages in the amount of approximately 3.5 million Euro for the wrongful termination of an implied distribution agreement with our company for Europe and parts of the Middle East. At the introductory hearing on April 1, 2003, the case was sent to the general docket. The Company believes this claim is without merit and intends to continue to defend the claim vigorously.

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

A hearing was held on April 29, 2003 regarding certain procedural issues. In a judgment rendered on May 27, 2003, the Judge of Seizures of the Court of First Instance referred the complaint to the Constitutional Court before rendering a final decision. The Judge of Seizures asked the Constitutional Court to render an opinion regarding certain constitutional issues related to the trademark infringement arguments the Company raised at the hearing. Hearings in the Constitutional Court were held on July 8, 2003 and September 9, 2003. On March 24, 2004, the Constitutional Court issued its judgment which supported the Company s claims. A hearing was scheduled for November 9, 2004 by the Judge of Seizures of the Court of First Instance to hear additional submissions. On December 21, 2004, the Judge of Seizures of the Court of First Instance decided against Euromedix s opposition to certain procedural issues.

After the decisions of the Judge of Seizures of the Court of First Instance, the Company filed requests for a procedural calendar in the three trademark infringement proceedings against Euromedix of which two are pending before the President of the Commercial Court of Leuven and one before the Commercial Court of Leuven. Both parties have exchanged submissions. All three cases were pleaded at a hearing on June 21, 2005 and were taken into deliberation. On September 13, 2005, a judgment was rendered in favor of the Company regarding items (i) and (ii) above. A judgment has not yet been rendered on item (iii).

Euromedix filed a request for a procedural calendar in the case pending before the Commercial Court of Leuven regarding the termination of the business relationship on July 11, 2002. On December 13, 2005, the Commercial Court of Leuven decided in an interim decision that the termination of the relationship is not governed by Belgian law, but Californian law and allowed the parties to file further submissions in order to substantiate the claims under Californian law. The case has been sent to the general docket.

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

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9. Comprehensive Income

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

	Thirteen Weeks Ended	
	June 30, 2006	June 24, 2005
Net income	$ 1,496	$ 1,592
Change in unrealized gain (loss) on investments, net	(13)	(66)
Total comprehensive income	$ 1,483	$ 1,526

10. Income Taxes

For the thirteen weeks ended June 30, 2006, the Company recorded a provision for income taxes of $1.1 million, for an effective tax rate of 42.5%. For the thirteen weeks ended June 24, 2005, the Company recorded a provision for income taxes of $1.0 million, for an effective rate of 38.6%. The effective rate increased as a result of non-deductible stock-based compensation expense resulting from the adoption of SFAS 123(R) and the lapse in the federal provision allowing a credit for qualifying research and development activity.

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

11. Warranties

The Company records an accrual for estimated warranty costs when revenue is recognized. Warranty covers repair costs of the LDX Analyzer and replacement costs of defective single-use test cassettes. The warranty period for the LDX Analyzer is one year and for single-use test cassettes is the shelf-life of the product. The warranty cost of the GDX Analyzer and test cartridges are the responsibility of the vendor. The Company has processes in place to estimate accruals for warranty exposure. The processes include estimated LDX Analyzer failure rates and repair costs, known design changes, and estimated replacement rates for single-use test cassettes. Although the Company believes it has the ability to reasonably estimate warranty expenses, unforeseeable changes in factors impacting the estimate for warranty could occur and such changes could cause a material change in the Company s warranty accrual estimate. Such a change would be recorded in the period in which the change was identified. Changes in the Company s product warranty liability during the thirteen weeks ended June 30, 2006 and June 24, 2005, respectively, were as follows (in thousands):

	Thirteen Weeks Ended	
	June 30, 2006	June 24, 2005
Balance at the beginning of the year	$ 208	$ 286
Accruals and charges for warranty for the year	43	79
Cost of repairs and replacements	(75)	(114)
Balance	$ 176	$ 251

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

Certain statements in this Quarterly Report on Form 10-Q are forward-looking statements within the meaning of federal securities laws. These statements relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our or our industry s actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by the forward-looking statements. These risks and other factors include those listed under Part II, Item 1A. Risk Factors and elsewhere in this Quarterly Report on Form 10-Q. In some cases, you can identify forward-looking statements by terminology such as may , will , should , expect , plan , anticipate , believe , estimate , predict , potential , continue or the negative of these terms or other comparable terminology. Forward-looking statements include, but are not limited to, the following statements: our beliefs regarding the positive impact of recent developments; and our expected capital expenditures. In evaluating these statements, you should specifically consider various factors, including the risks outlined under Part II, Item 1A. Risk Factors. 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.

The following discussion and analysis of our financial condition and results of operations should be read together with our condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q.

Overview

We are a leading provider of diagnostic tools and information for immediate risk assessment and therapeutic monitoring of heart disease and diabetes. We currently manufacture the Cholestech LDX® System (the LDX System), which includes the LDX Analyzer and a variety of single-use test cassettes and market the LDX System in the United States, Canada, Europe, Asia, Australia and Latin America. The LDX System, which is waived under the Clinical Laboratory Improvement Amendments (CLIA), allows healthcare providers to perform individual tests or combinations of tests with a single drop of blood from a fingerstick within approximately six minutes. Our current products measure and monitor blood cholesterol, related lipids, glucose, liver function and high sensitivity C-reactive protein, and are used to test patients at risk of or suffering from heart disease, diabetes and liver disease. The LDX System can also provide the Framingham Risk Assessment from the patient s results as measured on the lipid profile cassette. In the thirteen weeks ended June 30, 2006, revenue from sales of the LDX Analyzer, single-use test cassettes and accessories represented 97% of our revenue.

Our corporate headquarters is located in Hayward, California. All of our manufacturing, research, regulatory and administrative activities are conducted at this location. We sell our products through a

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worldwide network of over 85 distributors. We have 21 regional sales managers who coordinate and work with our distribution partners to identify and promote sales of our products. We also employ 13 technical service representatives who are responsible for field customer service and customer retention initiatives within our existing installed base of products.

We have experienced recent significant developments that we expect to have a positive impact on our company, including the following:

In May 2006, we announced that Flora pro.activ, the UK s leading cholesterol lowering brand, has selected the LDX System as part of the Test the Nation program. This is the second national heart health initiative that has used the LDX System. The Swiss Heart Foundation recently submitted results of its national screening program to the Swiss Health Ministry. The Test the Nation program is being run by Flora pro.activ, in association with H.E.A.R.T. UK, the Hyperlipidaemia Education and Research Trust. The program aims to provide the necessary information that will encourage people to find out what shape their heart is in and take responsibility for their heart health. The campaign kicked off at the start of April, 2006 and takes place at city centres, supermarkets and major events including the Flora London Marathon on April 23. Over the next four months, Unilever will be offering free heart health checks with fully qualified nurses and expert advice on diet and lifestyle. In addition to free blood pressure and cholesterol testing with a qualified nurse, everyone tested will receive a Complete Guide to Heart Health.

In June 2006, we announced a contract with the Mexican Ministry of Communication and Transportation to supply the LDX System, for the Direccion General de Proteccion y Medicina Preventiva en el Transporte (DGPMPT). As part of the agreement, the DGPMPT will initially acquire 42 LDX Systems and 25,000 lipid test cassettes which will be used in the national health and wellness initiative targeting commercial vehicle operators. The Direccion General de Proteccion y Medicina Preventiva regulates the safe movement of materials and people throughout Mexico, including the licensing of operators of taxis, buses, airplanes, railroad, ships and tractor trailers. Every year, more than 100,000 transportation workers must complete physical examinations to ensure that their health complies with the Ministry s standards for job qualification. Based on the results of a six-month pilot, the Ministry determined that the adoption of the LDX System was the most appropriate and cost effective method of providing cardiovascular screening in more than 40 health centers throughout Mexico.

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Results of Operations

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

	Thirteen Weeks Ended					
	June 30, 2006		June 24, 2005			
	Amount	% of revenue	Amount	% of revenue	Amount of Increase (Decrease)	Percent Increase (Decrease)
Revenue	$ 16,784	100%	$ 15,065	100%	$ 1,719	11%
Cost of revenue	5,599	33	5,472	36	127	2
Gross profit	11,185	67	9,593	64	1,592	17
Operating expenses						
Sales and marketing	3,888	23	3,312	22	576	17
Research and development	1,383	8	1,067	7	316	30
General and administrative	3,780	23	2,755	18	1,025	37
Total operating expenses	9,051	54	7,134	47	1,917	27
Income from operations	2,134	13	2,459	16	(325)	(13)
Interest and other income, net	468	3	133	1	335	252
Provision for income taxes	1,106	7	1,000	7	106	11
Net income	$ 1,496	9%	$ 1,592	11%	$ (96)	(6)%

Thirteen weeks ended June 30, 2006 and June 24, 2005

Revenue. For the thirteen weeks ended June 30, 2006, revenue increased $1.7 million or 11%, to $16.8 million from $15.1 million for the thirteen weeks ended June 24, 2005. The increase in revenue is primarily attributable to sales of single-use test cassettes which increased $1.1 million, or 9%, from $12.9 million for the thirteen weeks ended June 24, 2005 to $14.0 million for the thirteen weeks ended June 30, 2006. Revenue from sales of our LDX Analyzer increased $407,000, or 71%, to $984,000 for the thirteen weeks ended June 30, 2006 from $577,000 for the thirteen weeks ended June 24, 2005. Revenue from sales of our GDX Analyzer and related single-use test cartridges increased $59,000, or 14% to $481,000 for the thirteen weeks ended June 30, 2006 from $422,000 for the thirteen weeks ended June 24, 2005. Accessories sales increased $143,000, or 13%, to $1.3 million for the thirteen weeks ended June 30, 2006 from $1.1 million for the thirteen weeks ended June 24, 2005. We expect our revenue to increase as we continue to leverage our installed base.

For the thirteen weeks ended June 30, 2006, domestic revenue increased $1.3 million, or 10%, to $14.3 million from $13.0 million for the thirteen weeks ended June 24, 2005. Most of the domestic revenue increase related to revenue from single-use test cassettes, which increased $889,000, or 8%, to $12.2 million for the thirteen weeks ended

June 30, 2006 from $11.3 million for the thirteen weeks ended June 24, 2005. Domestic LDX Analyzer revenue increased $346,000, or 77%, to $794,000 for the thirteen weeks ended June 30, 2006 from $448,000 for the thirteen weeks ended June 24, 2005. The revenue increase was driven by an increase in LDX units placed as a result of our continued effort to establish strategic partnerships with companies such as AstraZeneca. Domestic revenue for our GDX

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Analyzer and related single-use test cartridges decreased $38,000, or 11%, to $323,000 for the thirteen weeks ended June 30, 2006 from $361,000 for the thirteen weeks ended June 24, 2005.

International revenue increased $413,000, or 20%, to approximately $2.4 million for the thirteen weeks ended June 30, 2006 from $2.0 million for the thirteen weeks ended June 24, 2005. International revenue is primarily related to pharmaceutical promotional programs which tend to occur in irregular patterns and are difficult to forecast. Most of the international revenue increase resulted from sales of single-use cassettes which increased $249,000 or 16%, to $1.8 million for the thirteen weeks ended June 30, 2006 from $1.6 million for the thirteen weeks ended June 24, 2005. Sales of the LDX Analyzer increased $61,000, or 47%, to $190,000 for the thirteen weeks ended June 30, 2006 from $129,000 for the thirteen weeks ended June 24, 2005. Additionally, international revenue for our GDX Analyzer and related products increased $96,000, or 154%, to $158,000 for the thirteen weeks ended June 30, 2006 from $62,000 for the thirteen weeks ended June 24, 2005.

Cost of Revenue. Cost of revenue includes direct labor, direct material, overhead and royalties. Cost of revenue increased $127,000, or 2%, to $5.6 million for the thirteen weeks ended June 30, 2006 from $5.5 million for the thirteen weeks ended June 24, 2005. The increase was primarily related to the increased sales volume during the quarter. Gross margin increased to 67% for the thirteen weeks ended June 30, 2006 compared to 64% for the thirteen weeks ended June 24, 2005. The increase in gross margin was driven by our continued manufacturing efficiencies combined with the positive impact related to the expiration of a royalty agreement in March 2006 which previously required us to pay a royalty of 2% on net sales of single-use test cassettes. In addition, $114,000 in stock-based compensation was recognized in accordance with SFAS 123(R). We expect gross margin to range from approximately 64% to 66% for the remainder of the fiscal year.

Sales and Marketing Expenses. Sales and marketing expenses include salaries, commissions, incentive compensation, travel and expenses for outside services related to marketing programs. Sales and marketing expenses increased $576,000, or 17%, to $3.9 million for the thirteen weeks ended June 30, 2006 from $3.3 million for the thirteen weeks ended June 24, 2005. The increase was mainly attributable to increased compensation related expenses due to higher headcount, primarily related to the Endo-PAT and Boule development efforts, and $144,000 in stock-based compensation recognized in accordance with SFAS 123(R). Additionally, increased travel costs and consulting fees contributed to the overall increase for the thirteen weeks ended June 30, 2006. As a percent of total revenue, sales and marketing expenses increased to 23% for the thirteen weeks ended June 30, 2006 from 22% for the thirteen weeks ended June 24, 2005. We expect sales and marketing expenses will decrease slightly as a percentage of total revenue for the remainder of the fiscal year.

Research and Development Expenses. Research and development expenses include salaries, incentive compensation, expenses for professional consulting and other miscellaneous outside services, supplies and depreciation of capital equipment. Research and development expenses increased $316,000, or 30%, to $1.4 million for the thirteen weeks ended June 30, 2006 from $1.1 million for the thirteen weeks ended June 24, 2005. The increase was attributable to increased compensation related expenses due to higher headcount and $53,000 in stock-based compensation recognized in accordance with SFAS 123(R). Additionally, laboratory supplies costs, which consists primarily of samples used for testing and chemicals, increased $185,000. As a percent of total revenue, research and development expenses increased to 8% for the thirteen weeks ended June 30, 2006 from 7% for the thirteen weeks ended June 24, 2005. We expect research and development expenses will remain consistent as a percentage of total revenue for the remainder of the fiscal year.

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General and Administrative Expenses. General and administrative expenses include compensation and benefits and expenses for outside professional services, including information services, legal and accounting. General and administrative expenses increased $1.0 million, or 37%, to $3.8 million for the thirteen weeks ended June 30, 2006 from $2.8 million for the thirteen weeks ended June 24, 2005. Compensation related costs increased $486,000 due to an increase in headcount and $414,000 in stock-based compensation recognized in accordance with SFAS 123(R). Additionally, outside professional services increased $416,000 due to legal fees incurred related to various business development activities and accounting and consulting fees associated with Sarbanes-Oxley Act of 2002 compliance. As a percent of total revenue, general and administrative expenses increased to 23% for the thirteen weeks ended June 30, 2006 from 18% for the thirteen weeks ended June 24, 2005. We expect general and administrative expenses will decrease as a percentage of total revenue for the remainder of the fiscal year.

Interest and Other Income, Net. Interest and other income, net, primarily reflects income from the investment of cash balances and marketable securities, less the fees charged by financial institutions. Interest and other income, net, increased $335,000, or 252%, to $468,000 for the thirteen weeks ended June 30, 2006 from $133,000 for the thirteen weeks ended June 24, 2005. The increases were primarily attributable to an increase in cash and marketable securities and an increase in interest rates from the prior year period.

Income Taxes. For the thirteen weeks ended June 30, 2006, we recognized an income tax provision of $1.1 million, compared to an income tax provision of $1.0 million for the thirteen weeks ended June 24, 2005. The effective tax rate was 42.5% for the thirteen weeks ended June 30, 2006 which represents the federal tax at the statutory rate and the average state rate for all jurisdictions in which we are subject to income tax. The increase in the effective rate is due to the non-deductible stock-based compensation expense resulting from the adoption of SFAS 123(R) and the lapse in the federal provision allowing a credit for qualifying research and development activity.

Liquidity and Capital Resources

Cash flow information for the thirteen weeks ended June 30, 2006 and June 24, 2005 was as follows (in thousands):

	June 30, 2006	June 24, 2005
Cash, cash equivalents, marketable securities and long-term marketable securities	$ 46,459	$ 34,681
Net cash provided by operating activities	3,071	1,723
Net cash used in investing activities	(4,698)	(997)
Net cash provided by financing activities	939	301
Net increase (decrease) in cash and cash equivalents	$ (688)	$ 1,027

We have financed our operations primarily through net cash provided by operations and employee stock option exercises. In addition, we have available a $4.0 million revolving bank line of credit agreement which was renewed in September 2005 and will expire in September 2008. While the agreement is in effect, we are required to deposit assets with a collective value, as defined in the line of credit agreement, equivalent to no less than 100% of the outstanding principal balance. Amounts outstanding under the line of credit bear interest at either our choice of 0.5% below the bank s prime rate

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or 1.00% above the LIBOR rate, depending on the payment schedule. There are currently no amounts outstanding under this line of credit and as a result, there were no limitations on our deposited assets.

Cash Provided by Operating Activities. The net cash provided by operations increased $1.4 million to $3.1 million for the thirteen weeks ended June 30, 2006 from $1.7 million for the thirteen weeks ended June 24, 2005. Net cash provided by operations was primarily attributable to net income of $1.5 million and $2.0 million of non-cash adjustments, including depreciation, stock-based compensation and deferred taxes. A $505,000 decrease in working capital, other than cash, resulted from a $760,000 decrease in accounts payable and accrued liabilities and accrued payroll and benefits primarily due to the payout of bonuses and commissions related to fiscal year 2006. Accounts receivable and prepaid and other assets also decreased $846,000 while inventories increased $463,000.

The net cash provided by operations of $1.7 million for the thirteen weeks ended June 24, 2005 was primarily attributable to net income of $1.6 million and $1.5 million of non-cash adjustments including depreciation. A $1.4 million increase in working capital, other than cash, resulted from decreases in accounts payable and accrued liabilities, accrued payroll and benefits, and other liabilities. Accounts receivable and prepaid and other current assets also decreased $894,000 which was offset by a $247,000 increase in inventories.

Cash Used in Investing Activities. Investing activities resulted in the net use of $4.7 million of cash during the thirteen weeks ending June 30, 2006. Spending on additional manufacturing and computer equipment and software accounted for $214,000 of capital expenditures. Net purchases of marketable securities during the period used an additional $4.5 million in cash. Over the remainder of the current fiscal year we intend to spend approximately $4.4 million on additional capital expenditures for production equipment and other long lived assets.

Investing activities resulted in the net use of $1.0 million of cash during the thirteen weeks ended June 24, 2005. Spending on additional manufacturing equipment, facilities improvements and software accounted for $877,000 of capital improvements, as well as a $120,000 net purchase of marketable securities during the period.

Cash Provided by Financing Activities. Cash provided by financing activities for both the thirteen weeks ended June 30, 2006 and June 24, 2005 related to the issuance of common stock pursuant to the employee stock incentive plans. We raised $811,000 and $301,000 from the incentive programs for the thirteen weeks ended June 30, 2006 and June 24, 2005, respectively.

We believe that our current cash and cash equivalents, short-term marketable securities and cash we expect to generate from operations, will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 12 months.

Critical Accounting Policies

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

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authoritative pronouncements, historical experience and other assumptions as the basis for making estimates. Actual results could differ from these estimates.

Except as set forth below, 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 31, 2006.

Stock-Based Compensation

Beginning April 1, 2006, we began accounting for stock options and shares issued under our employee stock purchase plan (ESPP) under SFAS 123(R), which requires the recognition of the fair value of equity based compensation. The fair value of stock options was estimated using a Black-Scholes option valuation model. This model requires us to make subjective assumptions in implementing SFAS 123(R), including expected stock price volatility, estimated life and estimated forfeitures of each award. The fair value of equity-based awards is amortized over the vesting period of the award, and we have elected to use the straight-line method. We make quarterly assessments of the adequacy of the tax credit pool to determine if there are any deficiencies which require recognition in the condensed statement of operations. Prior to the implementation of SFAS 123(R), we accounted for stock options and ESPP shares under the provisions of Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees (APB 25) and made pro forma footnote disclosures as required by SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure, which amended SFAS 123, Accounting for Stock-Based Compensation. Pro forma net income and pro forma net income per share disclosed in the footnotes to the condensed financial statements were estimated using a Black-Scholes option valuation model. The fair value of restricted stock was calculated based upon the fair market value of the Company s common stock at the date of grant.

We have elected to adopt the alternative transition method provided under the provisions of Financial Accounting Standards Board (FASB) Staff Position No. FAS 123(R) 3 Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards. The alternative transition method includes simplified methods to establish the beginning balance of the additional paid-in capital pool (APIC pool) related to the tax effects of employee stock-based compensation, and to determine the subsequent impact on the APIC pool and statements of cash flows of the tax effects of employee stock-based compensation awards that are outstanding upon adoption of SFAS 123(R).

Recent Accounting Pronouncements

In July 2006, the FASB issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement No. 109 (FIN 48), which clarifies the accounting for uncertainty in income tax positions. This Interpretation requires that we recognize in our financial statements the impact of a tax position if that position is more likely than not of being sustained on audit, based on the technical merits of the position. The provisions of FIN 48 are effective for us beginning March 31, 2007, with the cumulative effect of the change in accounting principle, if any, recorded as an adjustment to opening retained earnings. We are currently evaluating the impact of adopting FIN 48 on our financial position, cash flows, and results of operations.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

For quantitative and qualitative disclosures about market risk affecting us, see Item 7A, Quantitative and Qualitative Disclosures About Market Risk, of our Annual Report on Form 10-K for the fiscal year ended March 31, 2006, which is incorporated herein by reference. Our exposure to market risk has not changed materially since March 31, 2006.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures. Our management evaluated, with the participation of our Chief Executive Officer and our Chief Financial Officer, the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act of 1934, as amended) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective as of June 30, 2006 to ensure that information we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934 is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decision regarding required disclosure, and that such information is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

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

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PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

On August 2, 2002, N.V. Euromedix (Euromedix) filed suit against Cholestech in the Commercial Court in Leuven, Belgium (No. F5700-02), seeking damages for the wrongful termination of an implied distribution agreement with the Cholestech for Europe and parts of the Middle East. On November 7, 2002, the court dismissed the suit. On December 31, 2002, Euromedix filed another suit against Cholestech in the Commercial Court in Leuven, Belgium (No. B/02/00044), seeking damages in the amount of approximately 3.5 million Euro for the wrongful termination of an implied distribution agreement with Cholestech for Europe and parts of the Middle East. At the introductory hearing on April 1, 2003, the case was sent to the general docket. We believe this claim is without merit and intend to continue to defend the claim vigorously.

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

A hearing was held on April 29, 2003 regarding certain procedural issues. In a judgment rendered on May 27, 2003, the Judge of Seizures of the Court of First Instance referred the complaint to the Constitutional Court before rendering a final decision. The Judge of Seizures asked the Constitutional Court to render an opinion regarding certain constitutional issues related to the trademark infringement arguments we raised at the hearing. Hearings in the Constitutional Court were held on July 8, 2003 and September 9, 2003. On March 24, 2004, the Constitutional Court issued its judgment which supported our claims. A hearing was scheduled for November 9, 2004 by the Judge of Seizures of the Court of First Instance to hear additional submissions. On December 21, 2004, the Judge of Seizures of the Court of First Instance decided against Euromedix s opposition to certain procedural issues.

After the decisions of the Judge of Seizures of the Court of First Instance, we filed requests for a procedural calendar in the three trademark infringement proceedings against Euromedix of which two are pending before the President of the Commercial Court of Leuven and one before the Commercial Court of Leuven. Both parties have exchanged submissions. All three cases were pleaded at a hearing on June 21, 2005 and were taken into deliberation. On September 13, 2005, a judgment was rendered in favor of Cholestech regarding items (i) and (ii) above. A judgment has not yet been rendered on item (iii).

Euromedix filed a request for a procedural calendar in the case pending before the Commercial Court of Leuven regarding the termination of the business relationship on July 11, 2002. On December 13, 2005, the Commercial Court of Leuven decided in an interim decision that the

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termination of the relationship is not governed by Belgian law, but Californian law and allowed the parties to file further submissions in order to substantiate the claims under Californian law. The case has been sent to the general docket.

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

ITEM 1A. RISK FACTORS

The reader should carefully consider each of the risks and uncertainties we describe below, as well as all of the other information in this report. The risks and uncertainties we describe below are not the only ones we face. Additional risks and uncertainties which we are currently unaware of or that we currently believe to be immaterial could also adversely affect our business.

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

Our revenue and operating results have varied significantly from quarter to quarter in the past and may continue to fluctuate in the future. The following are some of the factors that could cause our revenue, operating results and margins to fluctuate significantly from quarter to quarter:

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

manufacturing problems, efficiencies, capacity constraints or delays;

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

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

product pricing and discounts;

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

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

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

competition from diagnostic companies with greater financial capital and resources;

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

additions or departures of our key personnel;

promotional program spending by both domestic and European pharmaceutical companies;

variations in the mix of products sold;

litigation or the threat of litigation; and

adoption of new accounting standards, such as SFAS 123R.

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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 ten United States patents, one German patent and have filed patent applications relating to our technology internationally under the Patent Cooperation Treaty and individual foreign patent applications. The risks of relying on the proprietary nature of our technology include:

- our pending patent applications may not result in the issuance of any patents, or, if issued, such patents may not offer protection against competitors with similar technology;
- our patents may be challenged, invalidated or circumvented in the future, and the rights created under our patents may not provide a competitive advantage;
- competitors, many of whom have substantially greater resources than us and have made substantial investments in competing technologies, may seek to apply for and obtain patents covering technologies that are more effective than ours. This could render our technologies or products obsolete or uncompetitive or could prevent, limit or interfere with our ability to make, use or sell our products either in the United States or in international markets;
- the medical products industry has been characterized by extensive litigation regarding patents and other intellectual property rights; and
- an adverse determination in litigation or interference proceedings to which we may become a party could subject us to significant liabilities to third parties or require us to seek licenses from third parties, which may not be available on commercially reasonable terms or at all.

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

For example, in fiscal year 2004, we entered into a settlement agreement and license agreement with Roche, which settled all existing patent litigation between the parties on a worldwide basis. As a part of the settlement, we pay Roche an ongoing royalty and Roche granted an irrevocable, non-exclusive,

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worldwide license to us for its patents related to HDL cholesterol. In addition, the parties also agreed upon a mechanism for the resolution of future patent infringement disputes. We believe that any such dispute resolution will confirm that our HDL cholesterol test cassette, currently under development, does not infringe Roche s patents. If however, upon the resolution of any such dispute, it is ultimately determined that our new HDL cholesterol test cassette is covered by Roche s patents, we will pay Roche the same ongoing royalty.

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

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

Our current products incorporate technologies that are the subject of patents issued to, and patent applications filed by, others. We have obtained licenses for certain of these technologies. We may in the future be required to negotiate to obtain licenses for new products. Some of our current licenses are subject to rights of termination and may be terminated. Our licensors may not abide by their contractual obligations and, as a result, may limit the benefits we currently derive from their licenses. We may be unable to renegotiate or obtain licenses for technology patented by others on commercially reasonable terms, or at all. We also may be unable to develop alternative approaches if we are unable to obtain licenses. Our future licenses may also not be adequate for the operation of our business. Failure to obtain, maintain or enforce necessary licenses on commercially reasonable terms or to identify and implement alternative approaches could prevent us from introducing our products and severely harm our business.

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

The market price of our common stock has in the past been, and in the future is likely to be, highly volatile. For example, between June 24, 2005 and June 30, 2006, the price of our common stock, as reported on the NASDAQ National Market System, has ranged from a low of $7.99 to a high of $14.38. These fluctuations could result in substantial losses for investors. Our stock price may fluctuate for a number of reasons including:

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

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

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

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

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

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

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

- third-party payors are increasingly scrutinizing and challenging the prices charged for both existing and new medical products and services;
- healthcare providers are moving toward a system in which employers are requiring participants to bear a greater burden of the cost of their healthcare benefits which could result in fewer elective procedures, such as the use of our products for diagnostic screening;
- general uncertainty regarding what changes will be made in the reimbursement methods used by third-party payors and how that will affect the use of products such as ours, which may deter healthcare providers from adopting the use of our products; and
- an overall escalating cost of medical products and services has led to and will continue to lead to increased pressures on the healthcare industry, both domestic and international, to reduce the cost of products and services, including products offered by us.

Market acceptance of our products in international markets is also dependent, in part, on the availability of reimbursement or funding, as the case may be, within prevailing healthcare systems. Reimbursement, funding and healthcare payment systems in international markets vary significantly by country and include both government sponsored healthcare and private insurance. Third-party reimbursement and coverage may not be available or adequate in either the United States or

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international markets, and current reimbursement or funding amounts may be decreased in the future. Also, future legislation, regulation or reimbursement policies of third-party payors may adversely affect demand for our products or our ability to sell our products on a profitable basis. Any of these events could materially harm our business.

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

We believe that the healthcare industry in the United States is likely to undergo fundamental changes due to current political, economic and regulatory influences. We anticipate that Congress, state legislatures and the private sector will continue to review and assess alternative healthcare delivery and payment systems. Potential alternatives include mandated basic healthcare benefits, controls on healthcare spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, the creation of large insurance purchasing groups, price controls and other fundamental changes to the healthcare delivery system. We expect legislative debate to continue in the future and for market forces to demand reduced costs. We cannot predict what impact the adoption of any federal or state healthcare reform measures, future private sector reform or market forces may have on our business. Any changes in the healthcare system could potentially have extremely negative effects on our business.

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

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

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

Our product sales are primarily made through our network of over 85 domestic and international distributors. As a result, our financial results, quarterly product sales, trends and comparisons are affected by fluctuations in the buying patterns of end-user customers and our distributors, and by the changes in inventory levels of our products held by these distributors. We have only limited visibility over the inventory levels of our products held by our domestic and international distributors. While we

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attempt to assist our distributors in maintaining targeted stocking level of our products, we may not consistently be accurate or successful. This process involves the exercise of judgment and use of assumptions as to future uncertainties including end-user customer demand, and the reaction of our distributors to our new quarterly pricing policy. Consequently, actual results could differ from our estimates. Inventory levels of our products held by our distributors may exceed or fall below the levels we consider desirable on a going-forward basis, which may harm our financial results due to unexpected buying patterns of our distributors or our ability to efficiently manage or invest in internal resources, such as manufacturing and shipping capacity, to meet the actual demand for our products.

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

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

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

- low levels of awareness of the availability of our technology in both the physician and other customer groups;
- the availability and pricing of other testing alternatives;
- a decrease in the amount of reimbursement for performing tests on the LDX System and the GDX System;

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

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

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

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

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

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

We believe our business will not grow significantly if we do not develop, acquire or form alliances for new tests and products to use in conjunction with the LDX System and the GDX System. Developing new tests involves many significant problems and risks, including:

research and development is a very expensive process;

research and development takes a very long time to result in a marketable product;

significant costs (including diversion of resources) may be incurred in development before knowing if the development will result in a test that is commercially viable;

a new test will not be successful unless it is effectively marketed to its target market;

the manufacturing process for a new test must be reliable, cost efficient and high volume and must be developed and implemented in a timely manner to produce the test for sale;

new tests must meet a significant market need to be successful; and

new tests must obtain proper regulatory approvals to be marketed.

We could experience difficulties that delay or prevent the successful development, introduction and marketing of new tests and products. For example, regulatory clearance or approval of any new tests or products may not be granted on a timely basis, or at all. We have experienced difficulties obtaining regulatory approval for tests in the past. Because the evaluation of applications by the FDA for CLIA waived status is not based on precisely defined, objectively measurable criteria, we cannot predict the likelihood of obtaining CLIA waived status for future products. In addition, our business strategy includes entering into agreements with clinical and commercial collaborators and other third parties for

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

We face risks from failures in our manufacturing processes

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

raw materials variations or impurities;

human error;

manufacturing process variances and impurities; and

decreased manufacturing equipment performance.

Our LDX manufacturing equipment 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 increase, we could be required to use our machinery more hours per day and the down time resulting from equipment failure could increase;

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

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

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

our newest manufacturing line is operating at production capability. Our failure to maintain production levels and operate this line at production capability for an extended period would impact our ability to increase our manufacturing capacity.

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

We believe we will be required to reduce manufacturing costs for new and existing test cassettes to achieve sustained profitability. We currently manufacture the majority of our dry chemistry cassettes on a single production line. A second manufacturing line is currently used for overflow production and for research and development purposes. The complexity and custom nature of our manufacturing process increases the amount of time and money required to add an additional manufacturing line. In addition, we may need to implement additional cassette manufacturing cost reduction programs. Failure to maintain full production levels for our newest 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 13% in fiscal year 2006 and 14% in fiscal year 2005. 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.

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.

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

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

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

Sales to a limited number of customers have accounted for a significant portion of our revenue in each fiscal period. We expect that sales to 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 approximately 66% of our revenue in fiscal year 2006. In fiscal year 2006, Physicians Sales and Service accounted for approximately 22% of our total revenue, Henry Schein Inc. accounted for approximately 11% and McKesson Medical Surgical accounted for approximately 7% of our total revenue. In fiscal year 2005, Physicians Sales and Service accounted for approximately 24% of our total revenue, Henry Schein Inc. accounted for approximately 9% and McKesson Medical Surgical accounted for approximately 7% of our total revenue. We have experienced periods in which sales to some of our major customers, as a percentage of total revenue, have fluctuated due to delays or failures to place expected orders. We do not have long-term agreements with any of our customers, who generally purchase our products pursuant to cancelable short-term purchase orders. If we were to lose a major customer or if orders by or shipments to a major customer were to otherwise decrease or be delayed, our operating results would be harmed.

While we believe that we currently have adequate internal control over financial reporting, we are exposed to risks from recent legislation requiring companies to evaluate internal control over financial reporting

Section 404 of the Sarbanes-Oxley Act of 2002 requires our management to report on and our independent registered public accounting firm to attest to the effectiveness of our internal control over financial reporting. We have an ongoing program to perform the system and process evaluation and testing necessary to comply with these requirements.

We expect to continue to incur significant expenses and to devote additional resources to Section 404 compliance on an ongoing basis. In addition, it is difficult for us to predict how long it will take to complete the assessment of the effectiveness of our internal control over financial reporting each year and we may not be able to complete the process on a timely basis. In the event that internal controls over financial reporting are not effective as defined under Section 404, we cannot predict how regulators will react or how the market prices of our shares will be affected. In addition, if we fail to maintain an effective system of internal control or if we were to discover material weaknesses in our internal control systems, we may be unable to produce reliable financial reports or prevent fraud and it could harm our results of operations and financial condition.

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

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

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

- the 510(k) clearance process, which generally takes from four to 12 months but may take longer; and
- the pre-market approval process, which is a longer and more costly process than a 510(k) clearance process, involves the submission of extensive supporting data and clinical information and generally takes one to three years but may take significantly longer.

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

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

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

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

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

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

Quality System Regulations, which requires manufacturers to be in compliance with Food and Drug Administration regulations;

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

other foreign regulations and state and local health, safety and environmental regulations, which include testing, control and documentation requirements.

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

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

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

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

If we are successful in achieving and maintaining market acceptance for the LDX System and the GDX System, we will be required to expand our operations, particularly in the areas of sales, marketing and manufacturing. As we expand our operations, this expansion will likely result in new and increased responsibilities for management personnel and place significant strain on our management, operating and financial systems and resources. To accommodate any such growth and compete effectively, we will be required to implement and improve our information systems, procedures and controls, and to expand, train, motivate and manage our work force. Our personnel, systems, procedures and controls may not be adequate to support our future operations. Any failure to implement and improve operational, financial and management systems or to manage our work force as required by future growth, if any, could harm our business and prevent us from improving our financial condition as a result of increased sales.

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

Our success depends in significant part on the continued service of certain key scientific, technical, regulatory and managerial personnel. Our success will also require us to continue to identify, attract,

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hire and retain additional highly qualified personnel in those areas. Competition for qualified personnel in our industry is very competitive due to the limited number of people available with the necessary technical skills and understanding of our industry. We may be unable to retain our key personnel or attract or retain other necessary highly qualified personnel in the future, which would harm the development of our business.

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

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

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

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.

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

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

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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

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

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

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SIGNATURES

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

CHOLESTECH CORPORATION

Date: August 9, 2006

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

Date: August 9, 2006

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

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INDEX TO EXHIBITS

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