CHOLESTECH CORPORATION
Form 10-Q
August 03, 2005

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

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

For the quarterly period ended June 24, 2005

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 an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).
Yes þ No o

As of June 24, 2005, 14,688,602 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, except per share data)

	June 24, 2005 (unaudited)	March 25, 2005(1)
Assets		
Current assets:		
Cash and cash equivalents	$ 5,331	$ 4,304
Marketable securities	20,389	19,574
Accounts receivable, net	4,128	4,651
Inventories, net	8,718	8,356
Prepaid expenses and other assets	1,562	1,889
Deferred tax assets	809	2,333
Total current assets	40,937	41,107
Property and equipment, net	8,367	8,176
Long-term marketable securities	8,961	9,590
Long-term deferred tax assets	15,800	15,248
Total assets	$ 74,065	$ 74,121
Liabilities and Shareholders Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,258	$ 4,259
Accrued payroll and benefits	1,979	2,984
Other liabilities	252	286
Total current liabilities	5,489	7,529
Contingencies (note 6)		
Shareholders equity:		
Common stock, no par value; 25,000,000 shares authorized; 14,688,602 and 14,614,914 shares issued and outstanding at June 24, 2005 and March 25, 2005, respectively	92,056	91,681
Accumulated other comprehensive income	(50)	(116)
Deferred compensation	(290)	(241)
Accumulated deficit	(23,140)	(24,732)

Total shareholders equity	68,576	66,592
Total liabilities and shareholders equity	$ 74,065	$ 74,121

(1) The information in this column was derived from the Company s audited consolidated financial statements as of the fiscal year ended March 25, 2005.

See Notes to Condensed Financial Statements

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

	Thirteen Weeks Ended	
	June 24, 2005	**June 25, 2004**
Revenue	$15,065	$ 9,553
Cost of revenue	5,472	4,004
Gross profit	9,593	5,549
Operating expenses:		
Sales and marketing	3,312	2,784
Research and development	1,067	902
General and administrative	2,755	2,443
Total operating expenses	7,134	6,129
Income (loss) from operations	2,459	(580)
Interest and other income, net	133	15
Income (loss) before provision for income taxes	2,592	(565)
Provision (benefit) for income taxes	1,000	(220)
Net income (loss)	1,592	$ (345)
Net income (loss) per share:		
Basic	$ 0.11	$ (0.02)
Diluted	$ 0.11	$ (0.02)
Shares used to compute income per share:		
Basic	14,618	14,163
Diluted	14,913	14,163

See Notes to Condensed Financial Statements

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

	Thirteen Weeks Ended	
	June 24, 2005	June 25, 2004
Cash flows from operating activities:		
Net income (loss)	$ 1,592	$ (345)
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	686	749
Stock-based compensation	25	
Change in allowance for losses on accounts receivable	(44)	(37)
Change in inventory reserve	(115)	(599)
Deferred tax asset	972	(170)
Changes in assets and liabilities:		
Accounts receivable	567	2,791
Inventories	(247)	(880)
Notes receivable		50
Prepaid expenses and other assets	327	558
Accounts payable and accrued expenses	(1,001)	110
Accrued payroll and benefits	(1,005)	127
Other liabilities	(34)	(41)
Net cash provided by operating activities	1,723	2,313
Cash flows from investing activities:		
Sales and maturities of marketable securities	6,710	5,087
Purchases of marketable securities	(6,830)	(6,810)
Purchases of property and equipment	(877)	(965)
Net cash used in investing activities	(997)	(2,688)
Cash flows from financing activities:		
Issuance of common stock	301	649
Net cash provided by financing activities	301	649
Net increase in cash and cash equivalents	1,027	274
Cash and cash equivalents at beginning of period	4,304	2,502
Cash and cash equivalents at end of period	$ 5,331	$ 2,776

See Notes to Condensed Financial Statements

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NOTES TO CONDENSED FINANCIAL STATEMENTS

1. Interim Results

The interim unaudited financial information of Cholestech Corporation (the Company) is prepared in conformity with accounting principles generally accepted in the United States of America. The financial information included herein has been prepared by management, without audit by an independent registered public accounting firm, and should be read in conjunction with the audited consolidated financial statements contained in the Annual Report on Form 10-K for the fiscal year ended March 25, 2005. 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 31, 2006.

2. Balance Sheet Data

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

	June 24, 2005	**March 25, 2005**
Raw materials	$ 2,524	$ 2,277
Work-in-process	2,116	2,395
Finished goods	4,078	3,684
	$ 8,718	$ 8,356

3. 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.

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4. Net Income (Loss) Per Share

Basic earnings per share is computed by dividing net income (loss) (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 or loss) and denominator (number of shares) used in the basic and diluted per share computations:

	Thirteen Weeks Ended	
(in thousands, except per share data)	June 24, 2005	June 25, 2004
Net income (loss)	$ 1,592	$ (345)
Shares		
Basic	14,618	14,163
Effect of dilutive securities	295	
Diluted	14,913	14,163
Per share net income (loss)		
Basic	$ 0.11	$ (0.02)
Effect of dilutive securities	0.00	0.00
Diluted	$ 0.11	$ (0.02)

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. As of June 25, 2004, options to purchase 2,255,488 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.

5. Stock-Based Compensation

The Company accounts for its stock-based compensation plans in accordance with SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS 123) as amended by SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure* (SFAS 148). As permitted under SFAS 148, the Company uses the intrinsic value-based method of Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), to account for its employee stock-based compensation plans. Under APB 25, compensation expense is based on the difference, if any, on the date of grant between the fair value of the Company s common shares and the exercise price of the option. Compensation costs for stock options, if any, are realized ratably over the vesting period. During the thirteen week period ended June 24, 2005, deferred compensation charged to operations related to restricted stock was $25,000.

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

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(in thousands, except per share data)	Thirteen Weeks Ended June 24, 2005	June 25, 2004
Net income (loss) as reported	$1,592	$ (345)
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	842
Pro forma net income (loss)	$ 924	$(1,187)
Net income (loss) per share:		
Basic		
As reported	$ 0.11	$ (0.02)
Pro forma	$ 0.06	$ (0.08)
Diluted		
As reported	$ 0.11	$ (0.02)
Pro forma	$ 0.06	$ (0.08)

The pro forma information presented above for the thirteen weeks ended June 25, 2004 has been revised from the information previously presented in the Company s Form 10-Q for the period ended June 25, 2004. Such pro forma disclosure may not be representative of future compensation costs because options vest over several years and additional grants are anticipated to be made each year.

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

	Thirteen Weeks Ended June 24, 2005	June 25, 2004
Risk free interest rate	3.73%	1.42%
Expected life	4.5 Years	7 Years
Expected volatility	65.0%	76.3%
Dividend yield	0.0%	0.0%

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

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6. Contingencies

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

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

A hearing was held on April 29, 2003 regarding certain procedural issues. In a judgment rendered on May 27, 2003, the Judge of Seizures of the Court of First Instance referred the complaint to the Constitutional Court before rendering a final decision. The Judge of Seizures asked the Constitutional Court to render an opinion regarding certain constitutional issues related to the trademark infringement arguments the Company raised at the hearing. 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 have been pleaded at a hearing on June 21, 2005 and have been taken into deliberation. A judgment has not yet been rendered.

Euromedix has 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. The Company has filed submissions and will file additional submissions by August 18, 2005. The case is set for pleadings at a hearing on November 8, 2005.

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On March 26, 2004, a putative class action lawsuit captioned Northshore Dermatology Center, S.C. v. Cholestech Corporation, and Does 1-10, Case No. 04CH05342, was filed in the Circuit Court of Cook County, Illinois. The Company was served with the complaint and summons on March 31, 2004. The complaint alleged that the Company violated the federal Telephone Consumer Protection Act and various Illinois state laws by sending unsolicited advertisements via facsimile transmission to residents of Illinois. The complaint sought class certification and statutory damages of $500 to $1,500 each on behalf of a class that would include all residents of Illinois who received an unsolicited facsimile advertisement from the Company. On January 18, 2005 the parties entered into an agreement to settle all claims on behalf of a nationwide class. Under the terms of the settlement, the Company paid $625,000 in cash to settle all claims, $600,000 of which was funded by insurance. The Company also agreed to pay up to $50,000 for providing notice to the class and for processing claims. The Court gave final approval to the settlement on July 11, 2005, and a final accounting is scheduled for November 2005.

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.

7. Comprehensive Income (Loss)

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

	Thirteen Weeks Ended	
	June 24, 2005	June 25, 2004
Net income (loss)	$1,592	$(345)
Change in unrealized gain on investments, net	(66)	(139)
Change in future currency contracts		9
Total comprehensive income (loss)	$1,526	$(475)

8. Income Taxes

For the thirteen weeks ended June 24, 2005, the Company recorded a provision for income taxes of $1 million for an effective tax rate of 39%. For the thirteen weeks ended June 25, 2004, the Company recorded a benefit for income taxes of $220,000, primarily resulting from the increase in the value of the net operating loss arising from the loss in the period.

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

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9. 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 24, 2005 and June 25, 2004, respectively, were as follows (in thousands):

	Thirteen Weeks Ended	
	June 24, 2005	**June 25, 2004**
Balance at the beginning of the year	$ 286	$ 314
Accruals and charges for warranty for the period	79	188
Cost of repairs and replacements	(114)	(229)
Balance	$ 251	$ 273

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

Certain statements in this Quarterly Report on Form 10-Q are forward-looking statements within the meaning of federal securities laws. These statements relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our or our industry s actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by the forward-looking statements. These risks and other factors include those listed under Factors Affecting Future Operating Results and elsewhere in this Quarterly Report on Form 10-Q. In some cases, you can identify forward-looking statements by terminology such as may , will , should , expect , plan , anticipate , believe , estimate , predict , potential , continue or the negative of these terms or other comparable terminology. Forward-looking statements include, but are not limited to, the following statements: recent significant developments that may have an impact on our company; anticipated future sales and marketing, research and development and general and administrative expenditures; anticipated income from cash and marketable securities and expected capital expenditures. In evaluating these statements, you should specifically consider various factors, including the risks outlined under Factors Affecting Future Operating Results . These factors may cause our actual results to differ materially from any forward-looking statement.

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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 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 five minutes. Our current products measure and monitor blood cholesterol, related lipids, glucose and liver function, 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 first thirteen weeks of fiscal year 2006, revenue from sales of the LDX Analyzer and single use test cassettes represented over 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 worldwide network of over 85 distributors. We have 23 regional sales managers who coordinate and work with our distribution partners to identify and promote sales of our products. We also employ 18 field 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 may have an impact on our company, including the following:

In June 2005, we announced that we had been granted a patent by the U.S. Patent Office (6,881,581) and the European Patent Office (EP 1,329,724) for a new method of measuring HDL in human blood. We believe that this patent provides a very different approach than those of other existing patents describing the measurement of HDL and that this patent also permits the development of the Cholestech LDX Lipid Profile/Alanine Amino-transferase (Lipid/ALT) cassette by preventing the interference of the HDL chemistry with the ALT assay on the same cassette.

In June 2005, we announced that the Cholestech LDX® System has been certified by the Cholesterol Reference Method Laboratory Network (CRMLN). This certification validates that the system consistently meets the gold standard for accuracy and reproducibility developed by the Centers for Disease Control and Prevention (CDC) for the measurement of total cholesterol and HDL cholesterol consistent with National Cholesterol Education Program (NCEP) analytical goals.

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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 24, 2005		June 25, 2004			
	Amount	% of sales	Amount	% of sales	Amount of Increase (Decrease)	Percent Increase (Decrease)
Revenue	$15,065	100%	$9,553	100%	$5,512	58%
Cost of revenue	5,472	36	4,004	42	1,468	37
Gross profit	9,593	64	5,549	58	4,044	73
Operating expenses						
Sales and marketing	3,312	22	2,784	29	528	19
Research and development	1,067	7	902	9	165	18
General and administrative	2,755	18	2,443	26	312	13
Total operating expenses						