CHOLESTECH CORPORATION
Form 10-Q
August 07, 2007

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 29, 2007

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 R No £

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 x	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 x

As of July 31, 2007, **15,630,756** shares of the registrant s common stock were outstanding.

CHOLESTECH CORPORATION

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PART I FINANCIAL INFORMATION

ITEM 1. CONDENSED FINANCIAL STATEMENTS

CHOLESTECH CORPORATION
CONDENSED BALANCE SHEETS
(in thousands, except share data)
(unaudited)

	June 29, 2007	March 30, 2007(1)
Assets		
Current assets:		
Cash and cash equivalents	$ 7,582	$ 6,561
Marketable securities	42,589	43,126
Accounts receivable, net	6,156	7,114
Inventories, net	8,759	9,102
Prepaid expenses and other assets	1,753	1,773
Deferred tax assets	2,199	1,835
Total current assets	69,038	69,511
Property and equipment, net	6,725	6,882
Intangible assets, net	394	414
Long-term marketable securities	17,766	12,765
Long-term deferred tax assets	9,280	10,334
Other long-term assets	743	795
Total assets	$ 103,946	$ 100,701
Liabilities and Shareholders Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,745	$ 2,880
Accrued payroll and benefits	2,436	3,379
Other liabilities	216	227
Total current liabilities	6,397	6,486
Commitments and Contingencies (note 8)		
Shareholders equity:		
Common stock, no par value; 25,000,000 shares authorized; 15,620,002 and 15,564,749 shares issued and outstanding at June 29, 2007 and March 30, 2007, respectively	105,435	103,948
Accumulated other comprehensive loss	(70)	(41)
Accumulated deficit	(7,816)	(9,692)
Total shareholders equity	97,549	94,215
Total liabilities and shareholders equity	$ 103,946	$ 100,701

(1) The information in this column was derived from the Company s audited financial statements as of the fiscal year ended March 30, 2007.

See Notes to Unaudited Condensed Financial Statements

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

	Thirteen Weeks Ended	
	June 29, 2007	**June 30, 2006**
Revenue	$ 18,129	$ 16,784
Cost of revenue	6,383	5,599
Gross profit	11,746	11,185
Operating expenses:		
Sales and marketing	3,647	3,888
Research and development	1,511	1,383
General and administrative	4,100	3,780
Total operating expenses	9,258	9,051
Income from operations	2,488	2,134
Interest and other income, net	786	468
Income before provision for income taxes	3,274	2,602
Provision for income taxes	1,292	1,106
Net income	$ 1,982	$ 1,496
Net income per share:		
Basic	$ 0.13	$ 0.10
Diluted	$ 0.12	$ 0.10
Shares used to compute income per share:		
Basic	15,494	14,824
Diluted	15,984	15,193

See Notes to Unaudited Condensed Financial Statements

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

	Thirteen Weeks Ended	
	June 29, 2007	**June 30, 2006**
Cash flows from operating activities:		
Net income	$ 1,982	$ 1,496
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	488	749
Stock-based compensation	808	776
Tax benefits from equity based compensation	129	179
Excess tax benefits from equity based compensation plans	(129)	(128)
Change in allowance for doubtful accounts	(15)	(2)
Change in inventory reserve	44	(17)
Change in deferred tax asset	584	523
Changes in assets and liabilities:		
Accounts receivable	973	397
Inventories	299	(463)
Prepaid expenses and other assets	20	449
Other long-term assets	52	(96)
Accounts payable and accrued expenses	865	380
Accrued payroll and benefits	(943)	(1,140)
Other liabilities	(11)	(32)
Net cash provided by operating activities	5,146	3,071
Cash flows from investing activities:		
Sales and maturities of marketable securities	76,208	14,272
Purchases of marketable securities	(80,701)	(18,756)
Purchases of property and equipment	(311)	(214)
Net cash used in investing activities	(4,804)	(4,698)
Cash flows from financing activities:		
Issuance of common stock	550	811
Excess tax benefits from equity based compensation plans	129	128
Net cash provided by financing activities	679	939
Net increase (decrease) in cash and cash equivalents	1,021	(688)
Cash and cash equivalents at beginning of period	6,561	7,161
Cash and cash equivalents at end of period	$ 7,582	$ 6,473

See Notes to Unaudited Condensed Financial Statements

CHOLESTECH CORPORATION
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 30, 2007. The information furnished includes all adjustments and accruals consisting only of normal recurring adjustments that are, in the opinion of management, necessary for a fair statement 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 28, 2008, 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 30, 2007. The Company s significant accounting policies reflect the adoption of Financial Accounting Standards Board (FASB) Interpretation No. 48 (FIN 48), *Accounting for Uncertainty in Income Taxes* effective March 31, 2007. The amounts reported upon adoption were accounted for as a cumulative-effect adjustment recorded to the beginning balance of accumulated deficit. The adoption of FIN No. 48 did not have a material impact on our financial position, results of operations or cash flows.

3. Recent Accounting Pronouncements

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities including an amendment of FAS 115 (SFAS No.159). SFAS No. 159 allows companies to choose, at specified election dates, to measure eligible financial assets and liabilities at fair value that are not otherwise required to be measured at fair value. Unrealized gains and losses shall be reported on items for which the fair value option has been elected in earnings at each subsequent reporting date. SFAS No. 159 also establishes presentation and disclosure requirements. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007 and will be applied prospectively. We are currently evaluating the impact of adopting SFAS No. 159 on our financial position, results of operations or cash flows.

In September 2006, the FASB issued Statement No. 157, Fair Value Measurements (SFAS 157). This standard defines fair value, establishes the framework for measuring fair value in accounting principles generally accepted in the United States and expands disclosure about fair value measurements. This pronouncement applies under other accounting standards that require or permit fair value measurements. Accordingly, this statement does not require any new fair value measurement. This statement is effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. We are currently evaluating the requirements of SFAS No. 157 and have not yet determined the impact on our financial statements.

In June 2006, the FASB reached consensus on Emerging Issues Task Force (EITF) Issue No. 06-3, *How Taxes Collected From Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement* (EITF 06-3). The scope of EITF 06-3 includes any tax assessed by a governmental authority that is directly imposed on a revenue-producing transaction between a seller and a customer, including sales, use, value added and excise taxes. EITF 06-3 provides that a company may adopt a policy of presenting taxes in the consolidated statement of operations on either a gross or net basis. If such taxes are significant, and are presented on a gross basis, the amounts of those taxes should be disclosed. The consensus on EITF 06-3 is effective for the interim and annual reporting periods beginning after December 15, 2006. The Company adopted EITF 06-3 on March 31, 2007. The Company records taxes collected from its customers and remitted to governmental authorities on a net basis in the condensed consolidated statement of operations and the adoption had no effect on the condensed consolidated financial statements.

4. Balance Sheet Data

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

	June 29, 2007	March 30, 2007
Raw materials	$ 3,322	$ 2,788
Work-in-process	2,128	2,569
Finished goods	3,309	3,745
	$ 8,759	$ 9,102

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	
	June 29, 2007	June 30, 2006
(in thousands, except per share data)		
Net income	$ 1,982	$ 1,496
Shares		
Basic	15,494	14,824
Effect of dilutive securities	490	369
Diluted	15,984	15,193
Per share net income		
Basic	$ 0.13	$ 0.10
Effect of dilutive securities	(0.01)	0.00
Diluted	$ 0.12	$ 0.10

As of June 29, 2007, options to purchase 44,750 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 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.

7. Stock-Based Compensation

Effective April 1, 2006, the Company adopted SFAS No. 123(R) using the modified prospective transition method. Under this 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 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 29, 2007 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.

The allocation of stock-based compensation expense by functional area for the thirteen weeks ended June 29, 2007 and June 30, 2006, was as follows (in thousands):

	Thirteen Weeks Ended	
	June 29, 2007	June 30, 2006
Cost of sales	$ 141	$ 125
Research and development	69	61
Sales and marketing	189	160
General and administrative	409	430
	$ 808	$ 776

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 29, 2007	June 30, 2006
Risk free interest rate	4.50 %	5.08 %
Expected life	4.2 Years	4.6 Years
Expected volatility	46.57 %	58.50 %
Dividend yield	0.0 %	0.0 %
Weighted-average grant-date fair value	$ 9.17	$ 7.43

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 4.7% 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 29, 2007:

	Outstanding Options	Weighted Average Exercise Price Per Share
Balance, March 30, 2007	1,776,083	$ 11.04
Granted	29,250	21.41
Exercised	(41,471)	10.18
Canceled	(13,679)	12.71
Balance, June 29, 2007	1,750,183	11.22

The following table summarizes information about stock options outstanding as of June 29, 2007:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number	Weighted Avg. Contractual Life (1)	Weighted Avg. Exercise Price	Number	Weighted Avg. Exercise Price
$5.50 - $7.99	231,824	4.1	$ 7.28	196,339	$ 7.32
$8.00 - $8.97	356,524	4.6	8.53	293,120	8.51
$8.98 - $10.94	500,735	5.0	10.24	313,519	10.25
$10.95 - $12.51	340,800	6.4	12.13	157,845	12.24
$12.52 - $21.41	320,300	5.7	17.67	175,530	17.52
	1,750,183	5.2	11.22	1,136,353	10.69

(1) years

At June 29, 2007 the aggregate intrinsic value of options outstanding was $18.8 million and the aggregate intrinsic value of outstanding options exercisable was $12.8 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. 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. During the thirteen weeks ended June 29, 2007 and June 30, 2006 the Company sold 7,773 and 9,241 shares of common stock, respectively, 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.

A summary of the changes in restricted stock outstanding under the Company s equity compensation plans during the thirteen weeks ended June 29, 2007 is below:

	Shares	Weighted Avg. Grant Date Fair Value	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
Restricted stock at March 30, 2007	92,098	$ 13.81	3.2	$ 2,025,235

Granted	9,925	21.41	4.0	218,251
Vested	(3,790)	17.80		(83,342)
Forfeited	(3,916)	13.69		(86,113)
Restricted stock at June 29, 2007	94,317	$ 14.68	3.1	$ 2,074,031

At June 29, 2007 the aggregate intrinsic value of restricted stock outstanding was $2.1 million and which will be recognized over the weighted average period of 3.1 years.

Shareholder rights plan

The board of directors has approved a shareholder rights plan (the Rights Plan) under which each outstanding share of common stock is accompanied by a right to purchase (the Right) one-thousandth of a share of Series A participating preferred stock at an exercise price of $95.00, 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. In January 2007, the board of directors approved an amendment of the Rights Plan that extended the term of the Rights Plan. The Rights expire on the earlier of (i) January 22, 2017 or (ii) the redemption or exchange of the Rights.

8. Commitments and 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 (No. B/02/00044), seeking damages in the amount of approximately 3.5 million Euros 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 Euros for each LDX-Analyzer sold, a penalty of 1,000 Euros for each cassette sold contrary to the prohibition and a 25,000 Euros 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 Euros 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. Euromedix has appealed the ruling of the Commercial Court of Leuven and the appeal will be initiated at a hearing on September 21, 2007 before the First Chamber of the Court of Appeal of Brussels.

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.

On April 23, 2007, the Board of Directors (the Board) of Cholestech Corporation (Cholestech) approved the payment of cash bonuses to Cholestech s executive officers in lieu of making annual stock option grants. The Board determined not to make such annual grants because Cholestech was in discussions with Inverness Medical Innovations Inc. regarding a potential acquisition (the Acquisition) of Cholestech. On June 4, 2007, the amounts of the cash bonuses became determinable. The total bonuses of $698,000 are payable upon the closing of the Acquisition to such executive officers employed on the date of the closing of the Acquisition. In addition, under the terms of existing change-of-control severance agreements between Cholestech and these executive officers, such bonuses may be grossed up in the event such compensation received by Cholestech s executive officers is subject to the excise tax imposed by Section 280G of the Internal Revenue Code. The gross-up provisions of the severance agreements can have the effect of substantially increasing the total amount of the bonuses payable to the executive officers.

9. Comprehensive Income

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

	Thirteen Weeks Ended	
	June 29, 2007	June 30, 2006
Net income	$ 1,982	$ 1,496
Change in unrealized loss on investments, net	(29)	(13)
Total comprehensive income	$ 1,953	$ 1,483

10. Accounting and Reporting of Uncertain Income Tax Position

In June 2006, the FASB issued Interpretation No. 48 (FIN 48), *Accounting for Uncertainty in Income Taxes An Interpretation of FASB Statement No. 109* effective for years beginning after December 15, 2006. FIN 48 contains a two-step approach to recognizing and measuring uncertain tax positions accounted for in accordance with SFAS No. 109, *Accounting for Income Taxes* (SFAS 109). The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement.

The Company adopted FIN 48 effective March 31, 2007. As a result of the adoption of FIN 48, the company recognized a reduction to its deferred tax asset of $106,000 for unrecognized tax benefits, which was accounted for as a cumulative-effect adjustment recorded to the beginning balance of the accumulated deficit.

The company s policy is to include interest and penalties related to unrecognized tax benefits within the provision for taxes on the consolidated condensed statements of operations under the provisions of FIN 48. As of the date of adoption of FIN 48, the Company has not accrued any material amounts for the payment of interest and penalties relating to unrecognized tax benefits.

The company files U.S. federal and U.S. state tax returns. The Company is currently not under examination in any jurisdiction related to income taxes and, in general, most tax years remain open due to net operating losses and credit carryovers.

Although timing of initiation, resolution and closure on audits is highly uncertain, we do not believe it is reasonably possible that our unrecognized tax benefits will materially change in the succeeding 12 months.

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 29, 2007 and June 30, 2006, respectively, were as follows (in thousands):

	Thirteen Weeks Ended	
	June 29, 2007	June 30, 2006
Balance at the beginning of the year	$ 196	$ 208
Accruals and charges for warranty for the year	88	43
Cost of repairs and replacements	(97)	(75)
Balance	$ 187	$ 176

12. Recent Developments

Cholestech Corporation and Inverness Medical Innovations, Inc. announced that they have entered into a definitive merger agreement pursuant to which Inverness will acquire Cholestech Corporation, in a stock for stock merger at a fixed exchange ratio of 0.43642 shares of Inverness common stock for each share of common stock of Cholestech. The merger is conditioned upon approval by Cholestech s shareholders as well as the satisfaction of regulatory and other customary conditions. Approval by the shareholders of Inverness is not required. The transaction is structured as a tax-free reorganization and is expected to close during the fall of 2007.

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

Certain statements in this Quarterly Report on Form 10-Q are forward-looking statements within the meaning of federal securities laws. These statements relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our or our industry s actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by the forward-looking statements. These risks and other factors include those listed under Factors Affecting Future Operating Results and elsewhere in this Quarterly Report on Form 10-Q. In some cases, you can identify forward-looking statements by terminology such as may , will , should , expect , plan , anticipate , believe , estimate , predict , potential , continue or the negative of these terms or other comparable terminology. Forward-looking statements include, but are not limited to, the following statements: our expectation regarding gross margin for the remainder of fiscal 2007, our expectation regarding future sales and marketing, research and development, and general and administrative expenses and interest and other income; our expected capital expenditures; our expectation regarding future demand for reduced costs; our expectation regarding GDX System s future contribution of revenue; our belief regarding the importance of developing, acquiring or forming alliances for new tests and products; our expectation regarding our reliance on a limited number of customers for a substantial portion of our revenue; and our expectation regarding expenses and resources related to Section 404 compliance. In evaluating these statements, you should specifically consider various factors, including the risks outlined under Factors Affecting Future Operating Results. These factors may cause our actual results to differ materially from any forward-looking statement.

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

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, inflammatory disorders 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 and liver function, and are used to test patients at risk of or suffering from heart disease, diabetes and liver disease. The high sensitivity C-reactive protein test is currently only approved for use in non-waived labs. 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 29, 2007, revenue from sales of the LDX Analyzer, single-use test cassettes and accessories represented 98% 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 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.

Recent Developments

Cholestech Corporation and Inverness Medical Innovations, Inc. announced that they have entered into a definitive merger agreement pursuant to which Inverness will acquire Cholestech Corporation, in a stock for stock merger at a fixed exchange ratio of 0.43642 shares of Inverness common stock for each share of common stock of Cholestech. The merger is conditioned upon approval by Cholestech s shareholders as well as the satisfaction of regulatory and other customary conditions. Approval by the shareholders of Inverness is not required. The transaction is structured as a tax-free reorganization and is expected to close during the fall of 2007.

On July 12, 2007, Cholestech launched its newest CLIA-waived test, Lipid Profile ALT. The new test panel, initially available on a limited basis, is designed for use with the Cholestech LDX(R) System and combines an ALT test with a lipid profile, providing total cholesterol, HDL cholesterol, LDL cholesterol, triglyceride and alanine aminotransferase (ALT) results from a single fingerstick within approximately five minutes. By testing at the point of care, the Lipid Profile ALT test allows physicians in the United States to immediately assess elevated cholesterol levels and liver damage at the same time allowing for more efficient medication dosage adjustments and safety monitoring on-the-spot.

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 29, 2007		June 30, 2006		Amount of Increase (Decrease)	Percent Increase (Decrease)
	Amount	% of revenue	Amount	% of revenue		
Revenue	$ 18,129	100 %	$ 16,784	100 %	$ 1,345	8 %
Cost of revenue	6,383	35	5,599	33	784	14
Gross profit	11,746	65	11,185	67	561	5
Operating expenses						
Sales and marketing	3,647	20	3,888	23	(241)	(6)
Research and development	1,511	8	1,383	8	128	9
General and administrative	4,100	23	3,780	23	320	8
Total operating expenses	9,258	51	9,051	54	207	2
Income from operations	2,488	14	2,134	13	354	17
Interest and other income, net	786	4	468	3	318	68
Provision for income taxes	1,292	7	1,106	7	186	17
Net income	$ 1,982	11 %	$ 1,496	9 %	$ 486	32 %

Thirteen weeks ended June 29, 2007 and June 30, 2006

Revenue. For the thirteen weeks ended June 29, 2007, revenue increased $1.3 million or 8%, to $18.1 million from $16.8 million for the thirteen weeks ended June 30, 2006. The increase in revenue is primarily attributable to sales of single-use test cassettes which increased $1.3 million, or 9%, from $14.0 million for the thirteen weeks ended June 30, 2006 to $15.3 million for the thirteen weeks ended June 29, 2007. During the thirteen weeks ended June 29, 2007, 2.3 million cassettes were sold compared to 2.2 million cassettes in the same period of the prior year. Revenue from sales of our LDX Analyzer increased $16,000, or 2%, to $1.0 million for the thirteen weeks ended June 29, 2007 from $984,000 for the thirteen weeks ended June 30, 2006. During the thirteen weeks ended June 29, 2007, 1,353 LDX Analyzers were sold or placed through promotion compared to 1,037 units in the same period of the prior year. Accessories sales were $1.3 million for the thirteen week period ended June 29, 2007 and for the thirteen weeks ended June 30, 2006. Revenue from sales of our GDX Analyzer, single-use test cartridges, and other products decreased $40,000, or 8%, to $440,000 for the thirteen weeks ended June 29, 2007 from $480,000 for the thirteen weeks ended June 30, 2006. The decrease was primarily due to a 12% decrease in GDX Analyzer and single use test cartridges sold during the thirteen weeks ended June 29, 2007 compared to the same period of the prior year. We expect our LDX product revenue to increase as we continue to penetrate existing customer accounts, develop new customer accounts, increase sales of our products, offer additional products, and enter new international markets.

For the thirteen weeks ended June 29, 2007, domestic revenue increased $1.2 million, or 8%, to $15.5 million from $14.3 million for the thirteen weeks ended June 30, 2006. Most of the domestic increase related to revenue from single-use test cassettes, which increased $1.3 million, or 11% to $13.5 million from $12.2 million in the prior year period. The increase was due to our continued efforts to sell or place through promotion LDX Analyzers, which resulted in a cassette volume related increase of $955,000. In addition, an increase in average sales price on cassettes contributed approximately $350,000. Accessories sales increased $100,000 or 10%, to $1.1 million for the thirteen week period ended June 29, 2007 from $1.0 million for the thirteen weeks ended June 30, 2006. LDX Analyzer revenue decreased $220,000, or 28%, to $563,000 for the thirteen weeks ended June 29, 2007 from $783,000 for the thirteen weeks ended June 30, 2006. The revenue decrease was attributable to promotions during the period in which certain end-users were provided a discounted LDX when they purchased a predetermined number of single-use test cassettes from our distribution partners. Domestic revenue for our GDX Analyzer, single-use test cartridges, and other products decreased $13,000, or 4%, to $309,000 for the thirteen weeks ended June 29, 2007 from $322,000 for the thirteen weeks ended June 30, 2006.

International revenue increased $200,000, or 8%, to approximately $2.6 million for the thirteen weeks ended June 29, 2007 from $2.4 million for the thirteen weeks ended June 30, 2006. International revenue is primarily related to pharmaceutical promotional programs which tend to occur in irregular patterns and are difficult to forecast. Most of the revenue increase resulted from LDX Analyzer which increased $260,000, or 137%, to $450,000 for the thirteen weeks ended June 29, 2007 from $190,000 for the thirteen weeks ended June 30, 2006. During the thirteen weeks ended June 29, 2007, 397 LDX Analyzers were sold or placed through promotion compared to 156 units in the same period of the prior year. International revenue for our the accessories decreased $33,000, or 13%, to $220,000 for the thirteen weeks ended June 29,

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2007 from $253,000 for the thirteen weeks ended June 30, 2006. GDX Analyzer and related products decreased $26,000 to $132,000 for the thirteen weeks ended June 29, 2007 from $158,000 for the thirteen weeks ended June 30, 2006. The international revenue decreases for both accessories and GDX Analyzer related products were due to fewer units sold during the thirteen weeks ended June 29, 2007 compared to the same period of the prior year.

Cost of Revenue. Cost of revenue includes direct labor, direct material, overhead and royalties. Cost of revenue increased $784,000, or 14%, to $6.4 million for the thirteen weeks ended June 29, 2007 from $5.6 million for the thirteen weeks ended June 30, 2006. Gross margin decreased to 65% for the thirteen weeks ended June 29, 2007 compared to 67% for the thirteen weeks ended June 30, 2006. The decrease in gross margin was primarily due to the underabsorption of overhead as activities related to the launch of Lipid Profile ALT caused production volumes for the quarter to be less than expected. We expect gross margin to range from approximately 66% to 68% 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 decreased $241,000, or 6%, to $3.6 million for the thirteen weeks ended June 29, 2007 from $3.9 million for the thirteen weeks ended June 30, 2006. The decrease was mainly attributable to a $204,000 decrease in marketing expenses, primarily related to distributor relations, marketing design, and trade show expenses that were incurred in fiscal 2007. Additionally, decreased travel related expenses of $82,000 and consulting fees of $76,000 contributed to the overall decrease during the thirteen weeks ended June 29, 2007. The decreases were offset by higher spending for the national sales meeting of $74,000. As a percent of total revenue, sales and marketing expenses decreased to 20% for the thirteen weeks ended June 29, 2007 from 23% for the thirteen weeks ended June 30, 2006. We expect sales and marketing expenses will increase 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 $128,000, or 9%, to $1.5 million for the thirteen weeks ended June 29, 2007 from $1.4 million for the thirteen weeks ended June 30, 2006. The increase was mainly attributable to higher consultant spending of $132,000 on LDX related projects and product development. As a percent of total revenue, research and development expenses were 8% for the thirteen weeks ended June 29, 2007 and for the thirteen weeks ended June 30, 2006. We expect research and development expenses will remain consistent as a percentage of total revenue for the remainder of the fiscal year.

General and Administrative Expenses. General and administrative expenses include compensation, benefits and expenses for outside professional services, including information services, legal and accounting. General and administrative expenses increased $320,000, or 8%, to $4.1 million for the thirteen weeks ended June 29, 2007 from $3.8 million for the thirteen weeks ended June 30, 2006. The increase was primarily due to approximately $625,000 in expenses related to the pending business combination with Inverness, including an increase of $206,000 in legal fees and $143,000 in accounting fees compared to the prior year quarter. As a percent of total revenue, general and administrative expenses were 23% for the thirteen weeks ended June 29, 2007 and thirteen weeks ended June 30, 2006. We expect general and administrative expenses will decrease slightly 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. Interest and other income, net, increased $318,000, or 68%, to $786,000 for the thirteen weeks ended June 29, 2007 from $468,000 for the thirteen weeks ended June 30, 2006. The increases were primarily attributable to an increase in cash and marketable securities.

Income Taxes. For the thirteen weeks ended June 29 2007, we recognized an income tax provision of $1.3 million, compared to an income tax provision of $1.1 million for the thirteen weeks ended June 30, 2006. The effective tax rate was 39.5% for the thirteen weeks ended June 29, 2007 which represents the federal tax at the statutory rate and the average blended state rate for all jurisdictions in which we are subject to income tax. The increase in the Provision for Income before Taxes for the three months ended June 29, 2007 is primarily results from the increase in Income Before Taxes, while the decrease in the effective tax rate is for the three months ended June 29, 2007 is primarily due to the re-enactment of the Federal Research Credit in December of 2006.

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.

Stock-Based Compensation. Effective April 1, 2006, we adopted SFAS No. 123(R) using the modified prospective transition method. Under this standard, stock-based compensation cost is measured at the grant date based on the calculated fair value of the award and is expensed over the vesting period of the option. For the three months ended June 29, 2007 we recorded $808,000 in stock-based compensation expense for employees. As of March 31, 2007, the total unamortized compensation cost related to unvested stock-based awards granted to employees under our stock incentive program, was approximately $5.4 million, net of forfeitures. The remaining weighted-average requisite service period of these options is approximately three years.

Liquidity and Capital Resources

Cash flow information for the thirteen weeks ended June 29, 2007 and June 30, 2006 was as follows (in thousands):

	June 29, 2007	June 30, 2006
Cash and cash equivalents, marketable securities and long-term marketable securities	$ 67,937	$ 46,459
Net cash provided by operating activities	5,146	3,071
Net cash used in investing activities	(4,804)	(4,698)
Net cash provided by financing activities	679	939
Net increase (decrease) in cash and cash equivalents, marketable securities and long-term marketable securities	$ 1,021	$ (688)

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 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 $2.0 million to $5.1 million for the thirteen weeks ended June 29, 2007 from $3.1 million for the thirteen weeks ended June 30, 2006. Net cash provided by operations was primarily attributable to net income of $2.0 million and $1.9 million of non-cash adjustments, including stock-based compensation, depreciation and a drecrease in deferred tax assets. A $1.2 million increase in working capital, other than cash, resulted from a $1.0 million decrease in accounts receivable and prepaid and other assets. In addition, inventories decreased $299,000, while accounts payable and accrued expenses and accrued payroll and benefits increased $78,000.

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.

Cash Used in Investing Activities. Investing activities resulted in the net use of $4.8 million of cash during the thirteen weeks ending June 29, 2007. Spending on additional manufacturing and computer equipment, facilities improvements and software accounted for $311,000 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 $2.1 million on additional capital expenditures for production equipment and other long lived assets.

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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.

Cash Provided by Financing Activities. Cash provided by financing activities for both the thirteen weeks ended June 29, 2007 and June 30, 2006 related to the issuance of common stock pursuant to the employee stock incentive plans, including the ESPP. We raised $679,000 and $939,000 million from the incentive programs for the thirteen weeks ended June 29, 2007 and June 30, 2006, 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 authoritative pronouncements, historical experience and other assumptions as the basis for making estimates. Actual results could differ from these estimates.

The Company s significant accounting policies are disclosed in the Company s Annual Report on Form 10-K for the year ended March 30, 2007. The Company s significant accounting policies reflect the adoption of Financial Accounting Standards Board (FASB) Interpretation No. 48 (FIN 48), *Accounting for Uncertainty in Income Taxes* effective March 31, 2007. The amounts reported upon adoption were accounted for as a cumulative-effect adjustment recorded to the beginning balance of accumulated deficit. The adoption of FIN No. 48 did not have a material impact on our financial position, results of operations or cash flows.

Recent Accounting Pronouncements

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities including an amendment of FAS 115 (SFAS No.159). SFAS No. 159 allows companies to choose, at specified election dates, to measure eligible financial assets and liabilities at fair value that are not otherwise required to be measured at fair value. Unrealized gains and losses shall be reported on items for which the fair value option has been elected in earnings at each subsequent reporting date. SFAS No. 159 also establishes presentation and disclosure requirements. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007 and will be applied prospectively. We are currently evaluating the impact of adopting SFAS No. 159 on our financial position, results of operations or cash flows.

In September 2006, the FASB issued Statement No. 157, Fair Value Measurements (SFAS 157). This standard defines fair value, establishes the framework for measuring fair value in accounting principles generally accepted in the United States and expands disclosure about fair value measurements. This pronouncement applies under other accounting standards that require or permit fair value measurements. Accordingly, this statement does not require any new fair value measurement. This statement is effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. We are currently evaluating the requirements of SFAS No. 157 and have not yet determined the impact on our financial statements.

In June 2006, the FASB reached consensus on Emerging Issues Task Force (EITF) Issue No. 06-3, *How Taxes Collected From Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement* (EITF 06-3). The scope of EITF 06-3 includes any tax assessed by a governmental authority that is directly imposed on a revenue-producing transaction between a seller and a customer, including sales, use, value added and excise taxes. EITF 06-3 provides that a company may adopt a policy of presenting taxes in the consolidated statement of operations on either a gross or net basis. If such taxes are significant, and are presented on a gross basis, the amounts of those taxes should be disclosed. The consensus on EITF 06-3 is effective for the interim and annual reporting periods beginning after December 15, 2006. The Company adopted EITF 06-3 on March 31, 2007. The Company records taxes collected from its customers and remitted to governmental authorities on a net basis in the condensed consolidated statement of operations and the adoption had no effect on the condensed consolidated financial statements.

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 30, 2007, which is incorporated herein by reference. Our exposure to market risk has not changed materially since March 30, 2007.

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 29, 2007 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.

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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 (No. B/02/00044), seeking damages in the amount of approximately 3.5 million Euros 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 Euros for each LDX-Analyzer sold, a penalty of 1,000 Euros for each cassette sold contrary to the prohibition and a 25,000 Euros 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 Euros 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. Euromedix has appealed the ruling of the Commercial Court of Leuven and the appeal will be initiated at a hearing on September 21, 2007 before the First Chamber of the Court of Appeal of Brussels.

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.

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.

Risks factors related to the pending merger between Inverness and the Company.

We have entered into a definitive merger agreement with Inverness pursuant to which Inverness would acquire the Company, in a stock-for-stock merger. The merger is subject to the satisfaction of customary closing conditions, including the receipt of Cholestech shareholder approvals to the merger. There can be no assurance that all of these conditions will be satisfied. If these conditions are not satisfied or waived, we may be unable to complete the merger and even if the merger is completed, the expected benefits to the combined company may not be realized. Below are

some of the risk factors related to the merger:

The integration of the operations of Inverness and Cholestech may be difficult and may lead to adverse effects.

The success of the merger will depend, in part, on the ability of Inverness to realize the anticipated synergies, cost savings and growth opportunities from integrating Cholestech s business with Inverness businesses. Inverness success in realizing these benefits and the timing of this realization depend upon the successful integration of the operations of Cholestech. The integration of two independent companies is a complex, costly and time-consuming process. The difficulties of combining the operations of the companies include, among others:

- consolidating manufacturing and research and development operations, where appropriate;
- integrating Cholestech s business into Inverness financial reporting system;
- coordinating sales, distribution and marketing functions;
- preserving the important licensing, research and development, manufacturing and supply, distribution, marketing, customer and other relationships of Cholestech;
- minimizing the diversion of management s attention from ongoing business concerns; and
- coordinating geographically separate organizations.

Inverness and Cholestech may not accomplish this integration smoothly or successfully. The diversion of the attention of management from its current operations to the integration effort and any difficulties encountered in combining operations could prevent Inverness from realizing the full benefits anticipated to result from the merger and adversely affect other Inverness businesses.

The price of Inverness common stock may decline, which would decrease the value of the merger consideration to be received by Cholestech stockholders in the merger.

The price of Inverness common stock might decline from the $48.17 price per share at the close of trading on June 1, 2007, the last full trading day prior to the public announcement of the merger. The exchange ratio will not be adjusted as a result of any change in the price of Inverness common stock or Cholestech common stock. Therefore, the value of the merger consideration to be received by Cholestech stockholders will depend on the market price of Inverness common stock at the time the merger becomes effective. Cholestech does not have the right to terminate the merger agreement or resolicit the vote of its stockholders based solely on changes in the value of Inverness common stock. Accordingly, if the price of Inverness common stock declines prior to the completion of the merger, the value of the merger consideration to be received by Cholestech stockholders in the merger will decrease as compared to the value on the date the merger was announced.

In addition, because the merger will be completed after the special meeting, Cholestech stockholders will not know the exact value of the Inverness common stock that will be issued in the merger when they vote on the merger proposal. As a result, a decline in the market price of Inverness

common stock after the special meeting will reduce the value of the merger consideration that Cholestech stockholders will receive.

During the twelve-month period ending on June 29, 2007, the price of Inverness common stock varied from a low of $25.99 to a high of $53.85.

Inverness and Cholestech may be unable to obtain the regulatory approvals required to complete the merger.

The merger is subject to review by the Antitrust Division and the FTC under the HSR Act. Under the HSR Act, Inverness and Cholestech were required to make pre-merger notification filings and await the expiration of the statutory waiting period. Inverness and Cholestech submitted the filings required by the HSR Act, and the waiting period expired on July 23, 2007. We do not believe that the merger is subject to review by any other governmental authorities under the antitrust laws of the other jurisdictions where Inverness and Cholestech conduct business.

While we expect to obtain required regulatory clearances, consents and approvals, we cannot be certain that any required approvals will be obtained, nor can they be certain that the approvals will be obtained within the time contemplated by the merger agreement. A delay in obtaining any required clearances, consents and approvals might delay and may possibly prevent the completion of the merger.

In addition, even after completion of the merger, either the Antitrust Division, the FTC, or other United States or foreign governmental authorities could challenge or seek to block the merger under the antitrust laws, as they deem necessary or desirable in the public interest. Moreover, in some jurisdictions, a competitor, customer or other third party could initiate a private action under the antitrust laws challenging or seeking to enjoin the merger, before or after it is completed. We cannot be sure that a challenge to the merger will not be made or that, if a challenge is made, Inverness and Cholestech will prevail.

The merger agreement limits Cholestech s ability to pursue alternatives to the merger.

The merger agreement contains provisions that make it more difficult for Cholestech to sell its business to a party other than Inverness. These provisions include the general prohibition on Cholestech soliciting any acquisition proposal or offer for a competing transaction, the requirement that Cholestech pay a termination fee of $9 million if the merger agreement is terminated in specified circumstances and the requirement that Cholestech submit the principal terms of the merger to a vote of Cholestech stockholders, even if the Cholestech board of directors changes its recommendation, unless, prior to the stockholder vote, Cholestech enters into a definitive agreement for a competing acquisition that its board of directors determines to be superior, terminates the merger agreement and pays the termination fee.

These provisions might discourage a third party that might have an interest in acquiring all of or a significant part of Cholestech from considering or proposing that acquisition, even if that party were prepared to pay consideration with a higher per share market price than the current proposed merger consideration. Furthermore, the termination fee may result in a potential competing acquiror proposing

to pay a lower per share price to acquire Cholestech than it might otherwise have proposed to pay. The payment of the termination fee could also have an adverse effect on Cholestech s financial condition.

Certain directors and executive officers of Cholestech have interests in the merger that may be different from, or in addition to, the interests of Cholestech stockholders.

When considering the Cholestech board of directors recommendation that Cholestech stockholders vote in favor of the proposal to approve the principal terms of the merger, Cholestech stockholders should be aware that some directors and executive officers of Cholestech have interests in the merger that may be different from, or in addition to, the interests of Cholestech stockholders. These interests include agreements that provide for payments following a change of control, including the acceleration of the vesting of stock options, and the right to continued indemnification and insurance coverage by Inverness for acts or omissions occurring prior to the merger. As a result of these interests, these directors and officers could be more likely to recommend a vote in favor of approval of the principal terms of the merger than if they did not hold these interests, and may have reasons for doing so that are not the same as the interests of other Cholestech stockholders.

Inverness expects to record a significant amount of goodwill and other intangible assets in connection with the merger, which may result in significant future charges against earnings if the goodwill and other intangible assets become impaired.

In connection with the accounting for the merger, Inverness expects to record a significant amount of goodwill and other intangible assets. Under SFAS No. 142, Inverness must assess, at least annually and potentially more frequently, whether the value of goodwill and other intangible assets has been impaired. Any reduction or impairment of the value of goodwill or other intangible assets will result in a charge against earnings, which could materially adversely affect Inverness results of operations in future periods.

Inverness faces different market risks from those faced by Cholestech, and these risks may cause the value of the shares of Inverness common stock issued to you to decline.

In the merger Cholestech shareholders will receive shares of Inverness common stock. The business, strategy and financial condition of Inverness are different from that of Cholestech. Inverness results of operations, as well as the price of Inverness common stock, will be affected by factors that may be different from those affecting Cholestech s results of operations and its common stock price.

Failure to complete the merger could negatively impact Cholestech s stock price and future business and operations.

If the merger is not completed for any reason, Cholestech may be subject to a number of material risks, including the following:

- Cholestech may incur approximately $1.25 million in merger-related expenses without realizing the expected benefits of the merger;

- Cholestech may be required to pay Inverness a termination fee of $9 million;

- the price of Cholestech common stock may decline to the extent that the current market price of Cholestech common stock reflects an assumption that the merger will be completed; and

- Cholestech must pay its accrued costs related to the merger, such as legal and accounting fees, even if the merger is not completed.

In addition, Cholestech s customers may, in response to the announcement of the merger, delay or defer purchasing decisions. Any delay or deferral in purchasing decisions by Cholestech customers could have a material adverse effect on Cholestech s business, regardless of whether or not the merger is ultimately completed. Similarly, current and prospective Cholestech employees may experience uncertainty about their future role with Inverness until Inverness strategies with regard to Cholestech are announced or executed. This uncertainty may adversely affect Cholestech s ability to attract and retain key management, marketing, technical, manufacturing, administrative, sales and other personnel.

Risk Factors Related to 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. As of June 29, 2007, we had an accumulated deficit of $7.8 million. We recorded net income of $9.4 million for fiscal year 2007, net income of $5.6 million for fiscal year 2006, and net income of $4.1 million for fiscal year 2005. 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;

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

- variations in the mix of products sold;

- promotional program spending by both domestic and European pharmaceutical companies;

- 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;

- 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; and

- litigation or the threat of litigation

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

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

Our success depends in part on our ability to develop and maintain the proprietary aspects of our technology and operate without infringing the proprietary rights of others. We have thirteen 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 December 2003, we entered into a settlement agreement and license agreement with Roche, which settled all existing patent litigation between the parties on a worldwide basis. As a part of the settlement, we pay Roche an ongoing royalty and Roche granted an irrevocable, non-exclusive, 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. Under the Roche license and settlement agreements, Cholestech is entitled to identify a design-around product that we believe does not require payment to Roche, and we have done so. Roche can request arbitration on this issue, and they have taken the first steps to initiate such proceedings. If no agreement is reached, an arbitration will be commended to determine whether license payments must be made for the design-around. If, 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, as that agreed to under the Roche license and settlement agreements.

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.

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

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

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

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

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

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

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

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

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

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

We believe that the healthcare industry in the United States is likely to undergo fundamental changes due to current political, economic and regulatory influences. We anticipate that Congress, state legislatures and the private sector will continue to review and assess alternative healthcare delivery and payment systems. Potential alternatives include mandated basic healthcare benefits, controls on healthcare spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, the creation of large insurance purchasing groups, price controls and other fundamental changes to the healthcare delivery system. We expect legislative debate to continue 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 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, we must demonstrate that the LDX System is a cost effective and time saving alternative 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 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 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 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.
- 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, 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, there can be no assurance that placement of these products will result in sustained demand for our single use test cassettes.

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, demand may not be sufficient to sustain revenue and profits from operations. Because the LDX System currently contributes the vast majority of our revenue, we could be required to cease operations if the LDX System does not achieve and maintain a significant level of market acceptance.

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

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

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

We could experience difficulties that delay or prevent the successful development, introduction and marketing of new tests and products. For example, regulatory clearance or approval of any new tests or products may not be granted on a timely basis, or at all. We have experienced difficulties obtaining regulatory approval for tests in the past. Because the evaluation of applications by the FDA for CLIA waived status is not based on precisely defined, objectively measurable criteria, we cannot predict the likelihood of obtaining CLIA waived status for future products. In addition, our business strategy includes entering into agreements with clinical and commercial collaborators and other third parties for the development, clinical evaluation and marketing of existing products and products under development. These agreements may be subject to rights of termination and may be terminated without our consent. The parties to these agreements also may not abide by their contractual obligations to us and may discontinue or sell their current lines of business. Research performed under a collaboration for which we receive or provide funding may not lead to the development of products in the timeframe expected, or at all. If these agreements are terminated earlier than expected, or if third parties do not perform their obligations to us properly and on a timely basis, we may not be able to successfully develop new products as planned, or at all.

We face risks from failures in our manufacturing processes

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

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

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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; and

- 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.

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 2007 and 2006, and approximately 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 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 65% of our revenue in fiscal year 2007. In fiscal year 2007, Physicians Sales and Service accounted for approximately 21% of our total revenue, Henry Schein Inc. accounted for approximately 10% and McKesson Medical Surgical accounted for approximately 8% of our total revenue. 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 significant 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.

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) pre-market notification process, which generally takes from two to four months but may take longer; and

- the pre-market approval process (PMA), 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 six months to a year 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, 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:

- ISO 13485:2003 requirements, which is an industry standard for maintaining and assuring conformance to quality management systems; and

- Canadian Medical Devices Conformity Assessment System (CMDCAS), which implements Canadian regulations requiring medical devices be designed and manufactured under a registered quality management system.

- 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.

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

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

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.

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 30, 2006 and June 29, 2007, the price of our common stock, as reported on the NASDAQ Stock Market LLC, has ranged from a low of $10.67 to a high of $22.44. 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.

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.

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

CHOLESTECH 2007 ANNUAL SHAREHOLDER MEETING AND RELATED SHAREHOLDER PROPOSALS

Cholestech will hold a 2007 annual meeting of shareholders only if the merger with Inverness is not completed. If Cholestech s 2007 annual meeting of shareholders is held after September 15, 2007, we shall, in a timely manner, inform our shareholders of the new date for the 2007 annual meeting of shareholders.

Any proposal of a stockholder of Cholestech that is intended to be presented by such stockholder at Cholestech s 2007 annual meeting of shareholders (if it is held) must have been received by Cholestech no later than March 19, 2007, in order for such proposal to be considered for inclusion in Cholestech s proxy statement and form of proxy relating to such meeting. However, if Cholestech s 2007 annual meeting of shareholders is held after September 15, 2007, then any such stockholder proposal must be received within a reasonable time before Cholestech begins to print and mail the proxy materials.

ITEM 6. EXHIBITS

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

31.2 Certification 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 7, 2007

/s/ Warren E. Pinckert II

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

Date: August 7, 2007

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

INDEX TO EXHIBITS

Exhibit No.	**Description**
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