

CHOLESTECH CORPORATION

Form 10-Q

August 09, 2002

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

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**FORM 10-Q**

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES AND EXCHANGE ACT OF 1934  
For the quarterly period ended June 28, 2002

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES AND 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**  
(State or other jurisdiction of  
incorporation or organization)

**94-3065493**  
(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 and Exchange Act of 1934 during the preceding 12 months (or for shorter period that the registrant was required to file such reports); and (2) has been subject to such filing requirements for the past 90 days. Yes  No

As of July 26, 2002, 13,597,840 shares of the registrant's common stock were outstanding.

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**Table of Contents****PART I FINANCIAL INFORMATION****ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**CHOLESTECH CORPORATION**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
(in thousands)

	June 28, 2002	March 29, 2002 (1)
	(unaudited)	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 10,730	\$ 8,800
Marketable securities	9,186	8,227
Accounts receivable, net	3,989	3,725
Inventories, net	5,511	4,973
Prepaid expenses and other current assets	1,248	1,153
	30,664	26,878
Property and equipment, net	7,610	7,589
Long-term investments	4,824	5,080
Goodwill, net	3,143	3,143
Other assets, net	59	61
	46,300	42,751
Total assets	\$ 46,300	\$ 42,751
<b>Liabilities and Shareholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 3,488	\$ 2,814
Accrued payroll and benefits	2,158	3,100
Other liabilities	101	116
	5,747	6,030
Total current liabilities	5,747	6,030
Contingencies		
Shareholders' equity:		
Common stock	81,553	79,200
Accumulated other comprehensive income	67	1
Accumulated deficit	(41,067)	(42,480)
	40,553	36,721
Total shareholders' equity	40,553	36,721
Total liabilities and shareholders' equity	\$ 46,300	\$ 42,751

(1) The information in this column was derived from the Company's audited consolidated financial statements for the fiscal year ended March 29, 2002.

See Notes to Condensed Consolidated Financial Statements



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

	Thirteen Weeks Ended	
	June 28, 2002	June 29, 2001
<b>Revenue:</b>		
Product	\$ 11,132	\$ 10,356
Service	436	2,022
Total revenue	11,568	12,378
<b>Cost of revenue:</b>		
Product	4,033	4,387
Service	291	603
Total cost of revenue	4,324	4,990
<b>Gross profit</b>	<b>7,244</b>	<b>7,388</b>
<b>Operating expenses:</b>		
Sales and marketing	3,828	3,574
Research and development	693	614
General and administrative	1,338	1,947
Website and related costs	77	77
Total operating expenses	5,859	6,212
Income from operations	1,385	1,176
Interest and other income, net	86	121
Income before provisions for income taxes	1,471	1,297
Provision for income taxes	58	52
<b>Net income</b>	<b>\$ 1,413</b>	<b>\$ 1,245</b>
<b>Net income per share:</b>		
Basic	\$ 0.11	\$ 0.10
Diluted	\$ 0.10	\$ 0.10
<b>Shares used to compute net income per share:</b>		
Basic	13,344	12,105
Diluted	14,483	12,508

See Notes to Condensed Consolidated Financial Statements





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	Thirteen Weeks Ended	
	June 28, 2002	June 29, 2001
Cash flows from operating activities:		
Net income	\$ 1,413	\$ 1,245
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Depreciation and amortization	622	618
Change in allowance for doubtful accounts	(2)	106
Change in inventory reserve	70	
Change in allowance for sales returns	25	
Changes in assets and liabilities:		
Accounts receivable	(287)	(1,746)
Inventories	(608)	(788)
Prepaid expenses and other assets	(95)	(47)
Accounts payable and accrued expenses	674	1,348
Payment of legal settlement		(855)
Accrued payroll and benefits	(942)	(28)
Other liabilities	(15)	25
	<u>855</u>	<u>(122)</u>
Cash flows from investing activities:		
Sales and maturities of marketable securities	10,491	3,463
Purchases of marketable securities	(11,128)	(3,349)
Purchases of property and equipment	(641)	(1,262)
	<u>(1,278)</u>	<u>(1,148)</u>
Cash flows from financing activities:		
Issuance of common stock	2,353	84
	<u>2,353</u>	<u>84</u>
Net increase (decrease) in cash and cash equivalents	1,930	(1,186)
Cash and cash equivalents at beginning of period	8,800	4,052
Cash and cash equivalents at end of period	<u>\$ 10,730</u>	<u>\$ 2,866</u>

See Notes to Condensed Consolidated Financial Statements

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## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

**1. Interim Results**

The interim unaudited financial information of Cholestech Corporation (the Company) is prepared in conformity with generally accepted accounting principles in the United States of America. The financial information included herein has been prepared by management, without audit by independent accountants, and should be read in conjunction with the audited consolidated financial statements contained in the Annual Report on Form 10-K for the fiscal year ended March 29, 2002. The information furnished includes all adjustments and accruals consisting only of normal recurring accrual adjustments that are, in the opinion of management, necessary for a fair presentation of results for the interim periods. Certain information or footnote disclosure normally included in the annual financial statements prepared in accordance with generally accepted accounting principles has been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission.

The interim results are not necessarily indicative of the results of operations for the full fiscal year ending March 28, 2003. Certain financial statement items have been reclassified to conform to the current year format.

**2. Balance Sheet Data**

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

	June 28, 2002	March 29, 2002
	_____	_____
Raw materials	\$ 1,459	\$ 1,573
Work-in-process	2,028	1,613
Finished goods	2,024	1,787
	_____	_____
	\$5,511	\$4,973
	_____	_____

**3. New Accounting Policies**

Derivative financial instruments are used by the Company in the management of its foreign currency exposures arising from inventory purchases and accounts payable denominated in foreign currencies. The Company does not use derivative financial instruments for trading or speculative purposes.

The Company uses financial instruments, such as forward exchange contracts, to hedge a portion of certain existing and anticipated foreign currency denominated transactions expected to occur within 12 months. The terms of currency instruments used for hedging purposes are generally consistent with the timing of the transactions being hedged. The purpose of the Company's foreign currency management is to manage the effect of exchange rate fluctuations on certain foreign currency denominated inventory costs and cash flows.

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The Company accounts for its derivative financial instruments in accordance with Statement of Financial Accounting Standards No. 133 ( SFAS 133 ), *Accounting for Derivative Instruments and Hedging Activities*. All of the Company's derivative financial instruments are recorded at fair value based upon quoted market prices for comparable instruments. For derivative instruments designated and qualifying as cash flow hedges of anticipated foreign currency denominated transactions, the effective portion of the gain or loss on these hedges is reported as a component of accumulated other comprehensive income/(loss) in stockholders' equity, and is reclassified into earnings when the related inventory is sold and the hedged transaction affects earnings. If the transaction being hedged fails to occur, a forecasted transaction being hedged is no longer expected to occur, or if a portion of any derivative is ineffective, the gain or loss on the associated financial instrument is recorded immediately in earnings. For derivative instruments used to hedge existing foreign currency denominated assets or liabilities, the gain or loss on these hedges is recorded immediately in earnings to offset the changes in the fair value of the assets or liabilities being hedged.

At June 28, 2002, the Company had outstanding forward contracts to purchase £762,000 for approximately \$1.2 million. The open contracts mature at various dates through April 17, 2003 and hedge certain forecasted inventory purchases denominated in the British Pound Sterling. The unrealized gains on the forward contracts at June 28, 2002 were \$4,000, all of which is expected to be reclassified to earnings within the next 12 months. There was no gain or loss recorded in the period from hedge ineffectiveness or from forecasted transactions no longer expected to occur. Due to increased committed and forecasted purchases, the Company entered into additional forward contracts to purchase £425,000 for approximately \$670,000 on July 25, 2002. The new contracts mature at various dates through March 21, 2003.

**4. Earnings Per Share**

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

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

(In thousands, except per share data)

	Thirteen Weeks Ended June 28, 2002			Thirteen Weeks Ended June 29, 2001		
	Net Income	Shares	Per Share	Net Income	Shares	Per Share
Basic EPS	\$ 1,413	13,344	\$ 0.11	\$ 1,245	12,105	\$ .010
Effect of dilutive securities		1,139	(0.01)		403	
Diluted EPS	\$ 1,413	14,483	\$ 0.10	\$ 1,245	12,508	\$ 0.10

As of June 28, 2002 options to purchase 449,162 shares of common stock were considered anti-dilutive because the respective exercise prices were greater than the average fair market value of the common stock. As of June 29, 2001 options to purchase 1,425,488 shares of common stock

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were considered anti-dilutive because the respective exercise prices were greater than the average fair market value of the common stock.

### **5. Recent Accounting Pronouncements**

In October 2001, the Financial Accounting Standards Board issued SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* ( SFAS No. 144 ), which was effective for the Company beginning April 1, 2002. SFAS No. 144 supersedes FASB Statement No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of* and addresses financial accounting and reporting for the impairment of certain long-lived assets and for the disposal of long-lived assets. The adoption of SFAS No. 144 did not have a material impact on financial reporting and related disclosures of the Company.

In November 2001, the Emerging Issues Task Force ( EITF ) issued EITF Issue No. 01-09, *Accounting for Consideration Given by a Vendor to a Customer/Reseller* ( EITF 01-09 ), which addresses the accounting for consideration given by a vendor to a customer, including both a reseller of the vendor's products and an entity that purchases the vendor's products from a reseller. EITF 01-09 also codifies and reconciles related guidance issued by the EITF, including EITF No. 00-25, *Vendor Income Statement Characterization of Consideration Paid to a Reseller of the Vendor's Products* ( EITF 00-25 ). EITF 01-09 outlines the presumption that consideration given by a vendor to a customer, a reseller or a customer of a reseller is to be treated as a deduction from revenue. Treatment of such payments as an expense would only be appropriate if two conditions are met: (i) the vendor receives an identifiable benefit in return for the consideration paid that is sufficiently separable from the sale such that the vendor could have entered into an exchange transaction with a party other than the purchaser or its products in order to receive that benefit; and (ii) the vendor can reasonably estimate the fair value of that benefit. EITF 01-09 is effective for fiscal years beginning after December 15, 2001. The Company adopted EITF No. 01-09 in the first quarter of fiscal year 2003. The Company's adoption of EITF No. 01-09 did not have a material impact on its financial position and results of operations.

### **6. Contingencies**

On December 23, 1999, a complaint entitled Roche Diagnostics GmbH v. Health Care Solutions AG, Euromedix N.V./SA and Cholestech Corporation was filed with the Canton Court of the Canton Zug in Zug, Switzerland by Roche Diagnostics seeking a cease and desist order barring the Company and two of its distributors from distributing HDL assay single-use test cassettes in Switzerland. The complaint alleges that the Company violated a Roche European patent for HDL. On July 11, 2000, the court denied the plaintiff's request for an injunction and ordered it to pay a portion of the Company's legal fees. On May 2, 2002, in response to the Company's motion, the court ruled that it did not have local jurisdiction over the Company and ordered the plaintiff to pay its legal fees. There can be no assurance as to whether the plaintiff will appeal this ruling or whether any additional action will be resolved in the Company's favor. At this point in time no schedule has been set regarding additional court activity.

In January 2000, a complaint, No. 4 O 4/00, was filed in the District Court, Dusseldorf, Germany by Roche Diagnostics against the Company, and two of its distributors, seeking a cease and desist order barring the distributors from shipping HDL single-use test cassettes into Germany. The complaint alleges the Company, and its distributors, violated a Roche German priority patent for HDL by selling its single-use test cassette containing a HDL assay. On December 4,

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2001, a hearing was held in Dusseldorf, Germany at which Cholestech and Roche witnesses testified. A hearing has been set for October 29, 2002. The Company believes the suit is without merit and intends to defend the case vigorously. However, there can be no assurance that the lawsuit will be resolved in the Company's favor.

On May 8, 2002, Roche Diagnostics extended the patent litigation suit to include an additional party, INCOMAT Medizinische Gerate GmbH. A preliminary hearing was held on July 9, 2002 in District Court, Dusseldorf, Germany. The court has not yet issued its ruling for the hearing.

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

In September 2000, a complaint, No. Ei/Ti ROCH 04002 was filed in Vienna, Austria by Roche Diagnostics, seeking a cease and desist order barring the Company and one of its distributors from distributing HDL assay single-use test cassettes in Austria. The complaint alleges that the Company violated a Roche European patent for HDL. On July 10, 2002, a hearing was held in the District Court in Vienna at which the District Court suspended the infringement suit. There can be no assurance as to whether the plaintiff will take any additional action or whether any additional action will be resolved in our favor.

The Company believes that it will ultimately prevail in the above complaints, however an adverse ruling could result in a material adverse impact on the Company's financial position, results of operations or cash flows in a future period. Additionally the Company is subject to various legal claims and assessments in the ordinary course of business, none of which are expected by management to result in a material adverse effect on the consolidated financial statements.

**7. Comprehensive Income**

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

(unaudited)	Thirteen Weeks Ended	
	June 28, 2002	June 29, 2001
Net income	\$ 1,413	\$ 1,245
Change in unrealized gain (loss) on investments, net	62	(10)
Foreign currency translation	4	
Total comprehensive income	\$ 1,479	\$ 1,235

**8. Segment Information**

The Company has two reportable segments, Diagnostic Products and WellCheck. The two segments are strategic business units that offer different products, and as a result, are managed separately. The accounting policies of the segments are consistent with the corporate accounting policies. Segment data excludes all corporate headquarters costs as they are not allocated to the operating segments, and inter-segment revenue is eliminated. Inter-segment revenue is recorded approximately at third-party purchase prices. Asset information by segment has not been presented as the Company does not produce such information.

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Results for the thirteen weeks ended June 28, 2002 and June 29, 2001 by segment are as follows (in thousands):

	Diagnostic Products		WellCheck		Inter-Company		Cholestech Segments	
	June 28, 2002	June 29, 2001	June 28, 2002	June 29, 2001	June 28, 2002	June 29, 2001	June 28, 2002	June 29, 2001
Net revenue	\$ 11,132	\$ 10,356	\$ 545	\$ 2,507	\$ (109)	\$ (485)	\$ 11,568	\$ 12,378
Cost of revenue	4,033	4,387	400	1,088	(109)	(485)	4,324	4,990
Gross profit	7,099	5,969	145	1,419			7,244	7,388
Operating expenses:								
Sales and marketing	3,184	2,382	644	1,100			3,828	3,482
Research and development	693	614					693	614
General and Administrative	38	212	82	500			120	712
Web site and related costs				77				77
Total operating expenses	3,915	3,208	726	1,677			4,641	4,885
Segment Income (loss) from Operations	\$ 3,184	\$ 2,761	\$ (581)	\$ (258)	\$	\$	\$ 2,603	\$ 2,503

Reconciliation of segment profit to the Company's consolidated totals (in thousands):

	June 28, 2002	June 29, 2001
Total income from operations for reportable segments	\$ 2,603	\$ 2,503
Unallocated corporate expenses	(1,218)	(1,327)
Interest income	86	121
Provision for income taxes	(58)	(52)
Net income	\$ 1,413	\$ 1,245

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

*Certain statements in this Management's Discussion and Analysis of Financial Condition and Results of Operations are forward looking statements. These statements relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by the forward looking statements. These risks and other factors include those listed under Risk Factors and elsewhere in this Quarterly Report on Form 10-Q. In some cases, you can identify forward-looking statements by terminology such as may, will, should, expect, plan, anticipate, believe, estimate, predict, potential, continue or the negative of these terms or other comparable terminology. These statements are only predictions. Actual events or results may differ materially. In evaluating these statements, you should specifically consider various factors, including the risks outlined under Factors Affecting Future Operating Results. These factors may cause our actual results to differ materially from any forward looking statement.*

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

**Overview**

We engage in two business activities:

Diagnostic Products develops, manufactures and markets our Cholestech LDX® System (the LDX System) and markets our Cholestech GDx System (the GDx System) which together perform diagnostic testing at sites outside of traditional hospital and clinical laboratories to assist in assessing for risk of heart disease, diabetes and certain liver diseases and in the monitoring of therapy to treat those diseases.

WellCheck conducts consumer testing within the United States of America to help assess the risk for heart disease and other chronic diseases. Through its Test Event Activity Management Software (TEAMS), WellCheck collects test results and other patient data (in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA)) and aggregates that data for testing event sponsors use in marketing programs.

Diagnostic Products currently manufactures and markets the LDX System, including the LDX Analyzer and a variety of single-use test cassettes, in the United States of America, Europe, Asia and South America. The LDX System allows healthcare providers to perform individual tests or combinations of tests with a single drop of blood from a fingerstick within five minutes. Our current products measure and monitor blood cholesterol, related lipids, glucose and liver function, and are used to test patients at risk of or suffering from heart disease, diabetes and liver disease. The LDX System can also provide the Framingham Risk Assessment from the patient's results as measured on the lipid profile cassette.

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Diagnostic Products also markets and distributes the GDX System under a multi-year global distribution agreement with Provalis Diagnostics Ltd., which was announced on May 21, 2002. Actual distribution of the GDX System, which also provides test results within five minutes and enables a physician's office or diabetes clinic to conduct diagnostic testing for hemoglobin A1c ( A1C ), began shipping in July 2002. A1C provides an average glucose level over a 90 day period, which can be used to assess the long term problems of a patient's diabetes and therapy management. On July 24, 2002 we announced that we signed an supply agreement with Abbott Laboratories for the GDX System. The initial purchase order in connection with this agreement was approximately \$700,000.

WellCheck, funded by third-party sponsors, uses the Cholestech LDX System to provide promotional health screenings for leading pharmaceutical, consumer product and corporate wellness clients in convenient consumer venues throughout the United States of America. These testing service activities result in additional sales of test cassettes manufactured by our Diagnostic Products business. WellCheck's professionals provide high quality services and offer test event expertise to both event sponsors and consumers. As part of our testing services, we utilize our proprietary TEAMS technology which automates registration, data acquisition and information management at testing events and provides participants with a personalized risk assessment for heart disease. Additionally, through this personalized risk assessment product, WellCheck provides its pharmaceutical, consumer product and other customers with analyses and insights into their targeted populations. WellCheck has developed its technology with the input of various authorities on health information privacy practices. TEAMS incorporates procedures that meet state and federal legislation, such as HIPAA, concerning the use of protected health information.

Substantially all of WellCheck's revenue is derived from promotional programs with major pharmaceutical companies marketing lipid-lowering statin drugs. We believe an opportunity exists to further expand our testing services business in the promotional and corporate wellness markets, along with other convenient venues which broaden consumer access to testing while assisting pharmaceutical and consumer product companies in customer acquisition. Our goal is to expand our testing services, thereby increasing sales of test cassettes manufactured by our Diagnostic Products business.

Our ongoing investment relating to WellCheck may result in continuing negative cash flows for this business unit. We intend to continue to make significant expenditures in sales, marketing, development and other areas to develop this business. The amount and timing of expenditures will have an impact on our ability to maintain profitability and positive cash flows.

As WellCheck's third party sponsorships evolve, the number of testing events and tests performed will vary and revenue will fluctuate. In an effort to diversify our customer base, we have established relationships with various third party sponsors for the current fiscal year, but the timing and level of some of these sponsorships have not yet been finalized. See "Factors Affecting Future Operating Results". Additionally, WellCheck's revenue will be influenced by seasonality. During the last two months of the calendar year, promotional testing decreases significantly as sponsors' budgets become fully spent. In addition, people typically pursue other interests and are less focused on chronic health issues during this time period.



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

	Thirteen Weeks Ended	
	June 28, 2002	June 29, 2001
<b>Revenue</b>		
Product	96%	84%
Service	4	16
Total	100	100
<b>Cost of revenue</b>		
Product	35	35
Service	2	5
Total	37	40
Gross profit	63	60
<b>Operating expenses</b>		
Sales and marketing	33	29
Research and development	6	5
General and administrative	12	16
Web site and other related costs		1
Total operating expenses	51	51
Income from operations	12	9
Interest and other income	1	1
Provision for income taxes	1	
Net income	12%	10%

**Thirteen weeks ended June 28, 2002 and June 29, 2001**

*Revenue.* During the thirteen weeks ended June 28, 2002 revenue decreased \$810,000, or 7%, to \$11.6 million from \$12.4 million for the thirteen weeks ended June 29, 2001. Diagnostic Products represented 96% and 84% of our revenue for the thirteen weeks ended June 28, 2002 and June 29, 2001, respectively. During the thirteen weeks ended June 28, 2002 and June 29, 2001 WellCheck represented 4% and 16% of our revenue, respectively, after inter-company eliminations.

International revenue decreased \$1.2 million, or 46%, to \$1.4 million for the thirteen weeks ended June 28, 2002, from \$2.6 million for the thirteen weeks ended June 29, 2001. Our Diagnostic Products segment generated all the international revenue.

Segment performance was as follows:

Diagnostic Products revenue increased \$776,000, or 7%, from \$10.4 million for the thirteen weeks ended June 29, 2001 to \$11.1 million for the thirteen weeks ended June 28, 2002. The increase primarily related to a \$1.3 million or 16% improvement in sales of single use test cassettes. However, sales of LDX analyzers decreased \$493,000 or 35% to \$923,000 from \$1.4 million for the thirteen weeks ended

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June 29, 2001. The decrease in LDX analyzers sales was largely attributed to a large one-time international pharmaceutical order in the prior year period.

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WellCheck revenue decreased \$2.0 million, or 78%, to \$545,000, before inter-company eliminations, for the thirteen weeks ended June 28, 2002 compared to \$2.5 million for the thirteen weeks ended June 29, 2001, before inter-company eliminations. The decrease primarily related to contracts with a single sponsor, which were completed in December 2001 and were not renewed. However, we have signed agreements with several new customers as part of our ongoing efforts to diversify our WellCheck customer base. As a result, we believe we are better positioned for future growth, but the lower value of the new agreements will result in unfavorable revenue comparisons for our second and third quarters of fiscal 2003 to the comparable periods in fiscal 2002. However, we expect to post favorable comparisons beginning in the fourth quarter of this fiscal year.

*Cost of Revenue.* Cost of revenue decreased \$666,000, or 13%, to \$4.3 million for the thirteen weeks ended June 28, 2002 from \$5.0 million for the thirteen weeks ended June 29, 2001. Gross margins were 63% and 60% for the thirteen weeks ended June 28, 2002 and June 29, 2001 respectively. Diagnostic Products accounted for 93% and WellCheck accounted for 7% of the cost of revenue, after inter-company eliminations, for the thirteen weeks ended June 28, 2002. For the thirteen weeks ended June 29, 2001 Diagnostic Products accounted for 88% and WellCheck accounted for 12% of the cost of revenue, after inter-company eliminations.

Segment performance was as follows:

Diagnostic Products cost of revenue includes direct labor, direct material, overhead and royalties. Cost of revenue decreased \$354,000, or 8%, to \$4.0 million for the thirteen weeks ended June 28, 2002 from \$4.4 million for the thirteen weeks ended June 29, 2001. Gross margins were 64% and 58% of total revenue for the thirteen weeks ended June 28, 2002 and June 29, 2001, respectively. The decrease in cost of revenue as a percentage of sales was primarily related to a product mix change to more sales of single use test cassettes. Additionally, productivity increased at a rate greater than factory spending for wages, depreciation and other material costs.

WellCheck cost of revenue includes travel expenses, TEAMS software depreciation and maintenance costs, laboratory services, medical waste disposal and the cost of medical testing equipment and supplies. Costs of product purchased from our Diagnostic Products business are eliminated upon consolidation. During prior periods, the cost of TEAMS software was included in our financial statements under the caption Website and Related Costs. Our consolidated financial statements for prior periods have been reclassified for comparative purposes.

For the thirteen weeks ended June 28, 2002 the total cost of revenue decreased \$688,000, or 63%, to \$400,000 from \$1.1 million for the thirteen weeks ended June 29, 2001. Gross margins were 27% and 57% of total revenue before inter-company eliminations for the thirteen weeks ended June 28, 2002, and June 29, 2001 respectively. The decrease was primarily attributable to a lower volume of testing and travel.

*Sales and Marketing Expenses.* Sales and marketing expenses include salaries, commissions, bonuses, travel and expenses for outside services related to marketing programs. Additionally, WellCheck sales and marketing expenses include salaries and related costs of associates who perform consumer testing. Sales and marketing expenses increased 7%, or \$254,000, to \$3.8 million for the thirteen weeks ended June 28, 2002, from \$3.6 million for the thirteen weeks ended June 29, 2001. Sales and marketing expenses increased to 33% of revenue for the thirteen weeks ended June 28, 2002, compared to 29% of revenue for the thirteen weeks ended June 29, 2001. Diagnostic Products accounted for 83% and WellCheck accounted for 17% of sales and marketing expenses for the thirteen

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weeks ended June 28, 2002. For the thirteen weeks ended June 29, 2001 Diagnostic Products accounted for 67%, WellCheck accounted for 31% and unallocated corporate amounts accounted for 2% of total sales and marketing expenses.

Sales and marketing expenses in each of our segments were as follows:

Diagnostic Products sales and marketing expenses increased \$802,000, or 34%, to \$3.2 million for the thirteen weeks ended June 28, 2002, from \$2.4 million for the thirteen weeks ended June 29, 2001. Sales and marketing expenses increased to 29% of revenue for the thirteen weeks ended June 28, 2002, from 23% for the thirteen weeks ended June 29, 2001. The increase was due to additional field sales associates, trade show, distributor relations and other promotional expenses.

WellCheck sales and marketing expenses decreased \$456,000, or 41%, to \$644,000 for the thirteen weeks ended June 28, 2002, from \$1.1 million for the thirteen weeks ended June 29, 2001. As a percentage of revenue, expenses increased to 118% of revenue, before inter-company eliminations, for the thirteen weeks ended June 28, 2002 from 44% for the thirteen weeks ended June 29, 2001. The decrease was related to lower spending for testing associates and related costs. We expect to continue to decrease expenses to better align with revenue.

There were no corporate sales and marketing expenses for the thirteen weeks ended June 28, 2002 as compared to \$92,000 for the thirteen weeks ended June 29, 2001. These expenses were related to a public relations marketing project which was completed during the first six months of the fiscal year.

*Research and Development Expenses.* Research and development expenses include salaries, bonuses, expenses for outside services, supplies and depreciation of capital equipment. Research and development expenses increased \$79,000, or 13%, to \$693,000, for the thirteen weeks ended June 28, 2002 from \$614,000 for the thirteen weeks ended June 29, 2001. Research and development expenses as a percentage of total revenue increased to 6% for the thirteen weeks ended June 28, 2002, from 5% for the thirteen weeks ended June 29, 2001. Our Diagnostic Products business represented 100% of our research and development expenses for both the thirteen weeks ended June 28, 2002 and June 29, 2001. Expenses increased \$79,000, or 13%, to \$693,000 for the thirteen weeks ended June 28, 2002 to \$693,000 compared to \$614,000 in the thirteen weeks ended June 29, 2001. The increase was attributable to wages and other staff related expenses and increased development material consumption.

*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 decreased \$609,000, or 31%, to \$1.3 million for the thirteen weeks ended June 28, 2002 from \$1.9 million for the thirteen weeks ended June 29, 2001. As a percentage of revenue, general and administrative expenses decreased to 12% for the thirteen weeks ended June 28, 2002, from 16% for the same period ended June 29, 2001. Unallocated corporate expenses represented 91%, Diagnostic Products represented 3% and WellCheck represented 6% of our general and administrative expenses for the thirteen weeks ended June 28, 2002. Unallocated corporate expenses accounted for 63%, Diagnostic Products accounted for 11% and WellCheck accounted for 26% of general and administrative expenses for the thirteen weeks ended June 29, 2001.

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General and administrative expenses in each of our segments were as follows:

Diagnostic Products general and administrative expenses decreased \$174,000 or 82% to \$38,000 for the thirteen weeks ended June 28, 2002, from \$212,000 for the thirteen weeks ended June 29, 2001. The decrease relates to the designation of the segment's Chief Operating Officer to be the corporate Chief Operating Officer. Following this change, the employee and related costs of this individual and administrative staff were recorded as a corporate expense.

WellCheck general and administrative expenses decreased \$418,000 or 84% to \$82,000 for the thirteen weeks ended June 28, 2002, from \$500,000 for the thirteen weeks ended June 29, 2001. The decrease relates to the elimination of the Chief Operating Officer position for this segment and related severance pay in the thirteen weeks ended June 29, 2001, and the transfer of one of the executives of this segment to the Chief Information Officer of our Company and the related transfer of expenses to corporate general and administrative expenses.

Corporate general and administrative expenses were \$1.2 million for both the thirteen weeks ended June 28, 2002 and June 29, 2001. Increases in expenses relating to the creation of the positions of corporate Chief Operating Officer and Chief Information Officer were offset by the elimination of the severance costs for the former Chief Financial Officer the thirteen weeks ended June 29, 2001.

*Website and Related Costs.* Website and related costs include expenses related to web hosting and related outside services. For the thirteen weeks ended June 28, 2002 there were no website and related costs compared to \$77,000 or 3% of revenue for the thirteen weeks ended June 29, 2001. The decline in costs relates entirely to the elimination of outside services to support the website. All website and related costs were attributable to the WellCheck segment.

*Interest and other income, net.* Interest and other income, net, reflects income from the investment of cash balances and marketable securities, and the fees charged by financial institutions. Interest income decreased \$35,000, or 29%, to \$86,000 for the thirteen weeks ended June 28, 2002, from \$121,000 for the thirteen weeks ended June 29, 2001. The decrease was the result of lower yields on investments and higher banking fees related to credit card processing services.

*Income Taxes.* For the thirteen weeks ended June 28, 2002 the provision for income taxes increased \$6,000, or 12%, to \$58,000 compared to \$52,000 for the thirteen weeks ended June 29, 2001. Since we have significant net operating losses and tax credit carryforwards, the provision for income taxes for the thirteen weeks ended June 28, 2002 primarily represents the estimated alternative minimum tax. Management expects to utilize additional net operating loss and other tax carryforward amounts to the extent income is earned during the remainder of the fiscal year ending March 28, 2003. Over the course of the next year, we will review our position on our valuation allowance. If we continue to remain profitable during the coming fiscal year, there is a possibility that we will release our valuation allowance. Prior to the release of the valuation allowance, to the extent that we are profitable, our effective tax rate should continue to be substantially less than the applicable statutory rates. Following the release of our valuation allowance, our effective tax rate will approximate the applicable statutory rates.

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**Liquidity and Capital Resources**

We have financed our operations primarily through the sale of equity securities and from positive cash flows from operations. From inception to June 28, 2002, we have raised \$81.6 million in net proceeds from equity financings. As of June 28, 2002 we had \$24.7 million of cash, cash equivalents and short and long-term marketable securities. In addition to these amounts, we have available an \$8.0 million revolving bank line of credit with Wells Fargo Bank, N.A. While the line of credit is in effect, we are required to deposit assets with a collective value, as defined in the line of credit agreement, equivalent to no less than 100% of the outstanding principal balance. Amounts outstanding under the line of credit bear interest at either our choice of 0.5% below the bank's prime rate or 1.75% above the LIBOR rate, depending on the payment schedule. The line of credit agreement expires on July 1, 2003. As of June 28, 2002 we had no borrowings outstanding under this line of credit.

During the thirteen weeks ended June 28, 2002, we generated \$855,000 of cash from operating activities compared to \$122,000 of cash used in the thirteen weeks ended June 29, 2001. The cash provided by operating activities for the thirteen weeks ended June 28, 2002 was comprised of net income of \$1.4 million and adjustments for non-cash items, including \$717,000 for depreciation, amortization and provision for excess and non-usable inventory reserve and product returns. Additionally, accounts payable and accrued expenses increased by \$674,000. This was offset by a \$942,000 decrease in accrued payroll and benefits, and increases of \$608,000 in inventory, \$287,000 in accounts receivable and \$95,000 in prepaid expenses. For the thirteen weeks ended June 29, 2001, cash provided was comprised of net income of \$1.2 million and adjustments for non-cash items, including \$724,000 of depreciation and provision for doubtful accounts. Additional cash was provided by a \$1.3 million increase in accounts payable and accrued expenses. This was consumed by a \$1.7 million increase in accounts receivable, a \$788,000 increase in inventory and an \$855,000 payment in settlement of our class action lawsuit.

Net cash used in investing activities was \$1.2 million in the thirteen weeks ended June 28, 2002 consisting primarily of the net purchase of \$637,000 in marketable securities and additional production and facility equipment costs of \$641,000. For the thirteen weeks ended June 29, 2001, we purchased \$1.3 million of capital equipment and had a net sale of \$114,000 of marketable securities.

Proceeds from our stock option exercises and stock purchase programs provided \$2.4 million in the thirteen weeks ended June 28, 2002. For the thirteen weeks ended June 29, 2001 \$84,000 was provided by exercises of options pursuant to our stock incentive and stock purchase programs.

During the remainder of the fiscal year ending March 28, 2003, we intend to expend approximately \$2.1 million for capital purchases related to tenant improvements, expansion of our manufacturing capacity, research and development and expansion of our information technology systems. As of June 28, 2002 however, no contracts have been signed and schedules have not been set with respect to these activities.

We believe that cash, cash equivalents, marketable securities, cash flows anticipated to be generated by future operations and available bank borrowings under an existing line of credit will be sufficient to meet our operating requirements for the foreseeable future. Despite this belief, however, we may require additional financing. We may be required to expend greater than anticipated funds if unforeseen difficulties arise relating to costs for WellCheck, facilities modification or expansion, obtaining necessary product regulatory approvals or scaling up manufacturing for new tests.

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Although we have now recorded net income in five consecutive quarters, we have historically experienced significant operating losses and operate in an industry subject to rapid technological changes. Management believes that there is sufficient uncertainty regarding our ability to generate future taxable income to utilize our net operating loss and tax credit carryforwards in future periods such that a full valuation allowance for deferred tax assets has been recorded as of June 28, 2002. Over the course of the next year, we will review our position on our valuation allowance. If we continue to remain profitable during the coming fiscal year, there is a possibility that we will release our valuation allowance. Prior to the release of the valuation allowance, to the extent that we are profitable, our effective tax rate should continue to be substantially less than the applicable statutory rates. Following the release of our valuation allowance, our effective tax rate will approximate the applicable statutory rates. If we continue to generate net income in fiscal 2003, it is reasonably possible that we will reduce, or eliminate, the valuation allowance in fiscal 2003. If this occurs, we will record a material benefit in the period of the valuation allowance reduced and in subsequent periods increase in the tax expense to approximately the prevailing corporate income tax rates.

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

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

## **Critical Accounting Policies**

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

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### **Derivative Financial Instruments**

Derivative financial instruments are used by the Company in the management of its foreign currency exposures arising from inventory purchases and accounts payable denominated in foreign currencies. The Company does not use derivative financial instruments for trading or speculative purposes.

The Company uses financial instruments, such as forward exchange contracts, to hedge a portion of certain existing and anticipated foreign currency denominated transactions expected to occur within 12 months. The terms of currency instruments used for hedging purposes are generally consistent with the timing of the transactions being hedged. The purpose of the Company's foreign currency management is to manage the effect of exchange rate fluctuations on certain foreign currency denominated inventory costs and cash flows.

The Company accounts for its derivative financial instruments in accordance with Statement of Financial Accounting Standards No. 133 ( SFAS 133 ), *Accounting for Derivative Instruments and Hedging Activities*. All of the Company's derivative financial instruments are recorded at fair value based upon quoted market prices for comparable instruments. For derivative instruments designated and qualifying as cash flow hedges of anticipated foreign currency denominated transactions, the effective portion of the gain or loss on these hedges is reported as a component of accumulated other comprehensive income/(loss) in stockholders' equity, and is reclassified into earnings when the related inventory is sold and the hedged transaction affects earnings. If the transaction being hedged fails to occur, a forecasted transaction being hedged is no longer expected to occur, or if a portion of any derivative is ineffective, the gain or loss on the associated financial instrument is recorded immediately in earnings. For derivative instruments used to hedge existing foreign currency denominated assets or liabilities, the gain or loss on these hedges is recorded immediately in earnings to offset the changes in the fair value of the assets or liabilities being hedged.

At June 28, 2002, the Company had outstanding forward contracts to purchase £762,000 for approximately \$1.2 million. The open contracts mature at various dates through April 17, 2003 and hedge certain forecasted inventory purchases denominated in the British Pound Sterling. The unrealized gains on the forward contracts at June 28, 2002 were \$4,000, all of which is expected to be reclassified to earnings within the next 12 months. There was no gain or loss recorded in the period from hedge ineffectiveness or from forecasted transactions no longer expected to occur. Due to increased committed and forecasted purchases, the Company entered into additional forward contracts to purchase £425,000 for approximately \$670,000 on July 25, 2002. The new contracts mature at various dates through March 21, 2003.

### **Recent Accounting Pronouncements**

In October 2001, the Financial Accounting Standards Board issued SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* ( SFAS No. 144 ), which was effective for the company beginning April 1, 2002. SFAS No. 144 supersedes FASB Statement No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of* and addresses financial accounting and reporting for the impairment of certain long-lived assets and for the disposal of long-lived assets. The adoption of SFAS No. 144 did not have a material impact on the Company's financial reporting and related disclosures.



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In November 2001, the Emerging Issues Task Force ( EITF ) issued EITF Issue No. 01-09, *Accounting for Consideration Given by a Vendor to a Customer/Reseller* ( EITF 01-09 ), which addresses the accounting for consideration given by a vendor to a customer, including both a reseller of the vendor's products and an entity that purchases the vendor's products from a reseller. EITF 01-09 also codifies and reconciles related guidance issued by the EITF, including EITF No. 00-25, *Vendor Income Statement Characterization of Consideration Paid to a Reseller of the Vendor's Products* ( EITF 00-25 ). EITF 01-09 outlines the presumption that consideration given by a vendor to a customer, a reseller or a customer of a reseller is to be treated as a deduction from revenue. Treatment of such payments as an expense would only be appropriate if two conditions are met: (i) the vendor receives an identifiable benefit in return for the consideration paid that is sufficiently separable from the sale such that the vendor could have entered into an exchange transaction with a party other than the purchaser or its products in order to receive that benefit; and (ii) the vendor can reasonably estimate the fair value of that benefit. EITF 01-09 is effective for fiscal years beginning after December 15, 2001. We adopted EITF No. 01-09 in the first quarter of fiscal year 2003. The adoption of EITF No. 01-09 did not have a material impact on our financial position and results of operations.

### **Factors Affecting Future Operating Results**

*We have limited experience in the testing services business, which will require significant management attention and financial resources to develop, and if this business is not successful, we may be harmed*

Our WellCheck testing services business, which we acquired in January 2000, is still relatively new to us and to our management team. In addition, the continued development of our testing services business will require significant management attention and financial resources. These expenditures are likely to materially affect our operating results as a whole. We may need to seek additional capital to help fund these expenses. The required additional capital may be unavailable to us at favorable or acceptable terms when required, or at all. If we cannot obtain the required additional capital, we may have to change our business strategy, which would be disruptive to our business. If we are not successful in developing this business, our Diagnostic Products business may be harmed. Even if we are successful at developing this business, the demands of attempting to grow this business may prevent us from devoting significant time and attention to our traditional Diagnostic Products business, and that business may decline.

*Our operating results may suffer if we are unable to manage geographically diverse operations*

We have managed and operated our traditional business almost exclusively from our Hayward, California headquarters. Our WellCheck business requires us to operate in multiple geographically dispersed locations and adapt our management and financial systems and controls to this geographically dispersed business. If we cannot successfully manage our geographic expansion, the testing services business may not succeed and we may not recover our investment in the testing services business. As a result, our business may suffer.

*If we are unable to expand third party sponsorship of our testing services business, or our existing sponsorship is eliminated or reduced, our revenue will be greatly reduced and our testing services business will fail*

WellCheck derives the majority of its revenue from third parties using our testing services to promote their products. For our testing services business to succeed, we must increase and diversify the current number of third-party relationships to grow our business.

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We have signed contracts with several new third-party sponsors in our continuing efforts to diversify our revenue base and are currently in discussions with potential third-party sponsors to establish relationships with WellCheck, but the timing and level of some of these sponsorships have not yet been finalized. For example, we have had discussions with AstraZeneca, one of our current sponsors, relating to our participation in the launch of its cholesterol-lowering drug Crestor. On August 6, 2002, AstraZeneca announced that the United States Food and Drug Administration (the FDA) has requested additional information relating to Crestor. The request will delay the expected launch date for this product, and therefore delay any revenue that we could potentially earn as a result of our potential participation in the launch of Crestor. If existing sponsors decline to participate in the future or reduce the amount of their sponsorship, our revenue will be greatly reduced and our testing services business will fail.

In addition, we periodically evaluate for impairment the \$3.1 million of goodwill capitalized upon the acquisition of our testing services business. If WellCheck is unsuccessful in achieving its projected revenue or future cash flows from WellCheck decline significantly, we may be required to take a charge relating to impairment of such goodwill. Such a charge would adversely impact our results of operations in the period in which the charge is taken.

### ***If we fail to integrate any future acquisitions, our business will be harmed***

We continue to evaluate strategic opportunities available to us and we may pursue product, technology or business acquisitions. These acquisitions could be very costly, could result in dilution to existing investors and could result in integration problems that harm our business as a whole. Any acquisition could result in expending significant amounts of cash, issuing potentially dilutive equity securities or incurring debt or unknown liabilities associated with the acquired business. Any of these acquisition financing approaches could materially harm our operating results and business. Acquisitions may also result in difficulties in assimilating the operations, technologies, products, services and personnel of the acquired company or business or in achieving the cost savings or other financial benefits we anticipated. These difficulties could result in additional expenses, diversion of management attention and an inability to respond quickly to market issues. Any of these results could harm us financially.

### ***Because we sell products internationally, we are subject to additional risks***

Historically, a significant portion of our total revenue has been revenue from outside of the United States. International revenue as a percentage of our total revenue was approximately 12% in the thirteen weeks ended June 28, 2002 and 21% in the thirteen weeks ended June 29, 2001. International revenue as a percentage of our total revenue was approximately 17% in both the fiscal years ended March 29, 2002 and March 30, 2001. 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, we make foreign currency denominated purchases related to the GDX System in the United Kingdom. This exposes us to risks associated with currency exchange fluctuations. To minimize this risk, we have undertaken certain foreign currency hedging transactions, and as a result, our future revenues from international operations may be unpredictable due to exchange rate fluctuations. Furthermore, a strengthening of the dollar could make our products less competitive in foreign markets.

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;
- political and economic instability;
- reduced protection for intellectual property rights in some countries;
- changes in tariffs and other trade barriers;
- difficulties in managing international operations; and
- potential insolvency of international distributors and difficulty in collecting accounts receivable collection and longer collection periods.

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

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

Our LDX System, including the LDX Analyzer and single-use test cassettes, currently accounts for substantially all of the revenue of our Diagnostics Products business. If this revenue does not grow, our overall business will be severely harmed. In addition, we have recently begun to distribute the GDX System, and it is uncertain whether this product will achieve broad market acceptance in our target markets and generate significant revenue in the future. For us to increase revenue, sustain profitability and maintain positive cash flows from operations, the LDX System and the GDX System must continue to and begin to gain broad 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 markets. Factors that could prevent broad market acceptance of the LDX System and the GDX System include:

low levels of awareness of the availability of our technology in both the physician and other customer groups;

the availability and pricing of other testing alternatives;

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

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

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

If our LDX System does not achieve broader market acceptance and our GDX System does not achieve favorable market acceptance, our Diagnostic Products business will not grow. Even if we are successful in continuing to place LDX Analyzers at physician office laboratories and other near-patient testing sites and initially marketing GDX Systems, there can be no assurance that placement of these products will result in sustained demand for our single-use test cassettes. We are relying in significant part on income from the core Diagnostic Product business to finance our strategic expansion.

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

***Our business has experienced a history of operating losses and fluctuating operating results, which may cause our stock price to fall***

Historically, we have experienced significant operating losses and negative cash flows from operations. As of June 28, 2002 we had an accumulated deficit of \$41.1 million. Our first profitable quarter was the third quarter of fiscal 1998, and our first profitable year was fiscal 1998. We recorded a net loss of \$2.6 million for fiscal 2001 and a net profit of \$5.6 million for fiscal 2002. Our profitability and positive cash flows from operations in the future will require:

broadening market acceptance of our existing product offerings;

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successfully developing, introducing and marketing additional test cassettes or other products for our Diagnostic Products business; and  
successfully developing our testing services business.

***Our quarterly operating results may fluctuate on a quarter to quarter basis, which could cause our stock price to decline***

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

- the timing and amount of expenditures required for the continued development of our testing services business;
- the timing and level of market acceptance of the LDX System and the GDx System;
- the timing of the introduction, availability and market acceptance of new tests and products;
- the timing and level of expenditures associated with research and development activities;
- variations in manufacturing efficiencies;
- the timing and establishment of strategic distribution arrangements and the success of the activities conducted under such arrangements;
- changes in demand for our products based on changes in third party reimbursement, competition, changes in government regulation and other factors;
- the timing of significant orders from, and shipments, to customers;
- product pricing and discounts;
- goodwill impairment;
- the timing and level of third-party sponsorship of our testing services business;
- seasonality of our testing business;
- variations in the mix of products sold; and  
general economic conditions.

These and other factors are difficult to predict and could have a material adverse effect on our business, financial condition and operating results. Fluctuations in quarterly demand for our products may cause our manufacturing operations to fluctuate in volume, increase uncertainty in operational planning and/or affect cash flows from operations. Many of our expenses are committed to 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 could cause the trading price of our common stock to decline significantly.

***If we do not successfully develop, introduce and market new tests and products, our business will be harmed***

Most of our revenue comes from our Diagnostics Products business. We anticipate this will continue for the foreseeable future. We also rely on revenue from the Diagnostics Products business to fund the development of our testing services business. We believe our Diagnostic Products business will not grow significantly if we do not develop new tests and products to use in conjunction with the

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LDX System and the GDx System. If new tests and products are not developed and accepted in the market, our business will not grow significantly and will be harmed. Developing new tests involves many significant problems and risks, including:

research and development is a very expensive process;

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

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

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

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

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

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 FDA's evaluation of applications for CLIA waived status is not based on precisely defined, objectively measurable criteria, we cannot predict the likelihood of obtaining waived status for future products.

***We face risks from failures in our manufacturing processes***

We manufacture all of the single-use test cassettes that are used with the LDX Analyzer. The manufacture of single-use test cassettes is a highly complex and precise process that is sensitive to a wide variety of factors. We have, in the past, 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 results of operations could be materially adversely affected. We may reject or be unable to sell a substantial percentage of test cassettes because of:

raw materials variations or impurities;

manufacturing process variances and impurities; and

decreased manufacturing equipment performance.

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

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

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

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

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

we are currently in the process of scaling up our recently installed third manufacturing line to full production capability. Our failure to increase production levels and operate this line at full production capability for an extended period would impact our ability to increase our manufacturing capacity.

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

We believe we will be required to reduce manufacturing costs for new and existing test cassettes to achieve sustained profitability. We currently operate three manufacturing lines for dry chemistry cassettes. We have recently installed our third manufacturing line, and we are currently in the process of scaling it up to full production capability. The complexity and custom nature of our manufacturing process increases the amount of time and money required to add an additional manufacturing line. Despite our efforts, the new manufacturing line may not operate at full production volume for a substantial period of time. Also, we may need to implement additional cassette manufacturing cost reduction programs. Failure to fully integrate the new dry chemistry manufacturing line could prevent us from satisfying customer orders in a timely manner, which could lead to customer dissatisfaction and loss of business. Failure to fully integrate the new line could also prevent us from reducing manufacturing costs for dry chemistry tests, and prevent us from achieving sustained profitability.

***We depend on single source suppliers for inputs to our manufacturing process and failure of our suppliers to provide supplies 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.

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

If we are successful in achieving and maintaining market acceptance for the LDX System, the GDX System, and our testing business, we will be required to expand our operations, particularly in the areas of sales, marketing and manufacturing. As we expand our operations, this expansion will likely result in new and increased responsibilities for management personnel and place significant strain on our management, operating and financial systems and resources. To accommodate any such growth and compete effectively, we will be required to implement and improve our information systems, procedures and controls, and to expand, train, motivate and manage our work force. Our personnel, systems,

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procedures and controls may not be adequate to support our future operations. Any failure to implement and improve operational, financial and management systems or to manage our work force as required by future growth, if any, could harm our business and prevent us from improving our financial condition as a result of increased sales.

***We depend on distributors to sell our products and will need to maintain and expand these existing relationships***

To increase revenue and achieve sustained profitability, we will have to maintain and expand our existing distribution relationships and develop new distribution relationships. We are dependent on such distributors to assist us in promoting market acceptance of the LDX System and the GDX System. If we do not maintain and expand these relationships, our sales will not grow and our business will be greatly harmed. Also, 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. We do not have the ability to prevent distributors from distributing products that compete with our products. The distributors may also give higher priority to the products of our competitors.

***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 67% of our revenue in fiscal 2002. In fiscal 2002, Physician Sales and Service, Inc. ( PSSI ) accounted for approximately 18% of our total revenue and GMR Marketing ( GMR ) accounted for 14% of our total revenue. In fiscal 2001, PSSI accounted for approximately 16% of our total revenue and GMR 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. For example, we do not expect GMR to account for any portion of our total revenue in fiscal 2003. 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 results of operations would be harmed.

***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 of America, healthcare providers that purchase products such as the LDX System and the GDX System generally rely on third party payors, 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:

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third party payors increasingly scrutinize and challenge the prices charged for medical products and services;

healthcare providers are moving toward a managed care system in which they provide comprehensive healthcare for a fixed cost per patient and authorize fewer elective procedures, such as uses 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 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 within prevailing healthcare systems. Reimbursement and healthcare 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 of America or international markets, and current reimbursement 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 of America undergoes fundamental change, these changes may harm our business***

We believe that the healthcare industry in the United States of America 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.

***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 America 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



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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 of 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 waived status. Food and Drug Administration clearance or approval of products such as ours can be obtained by either of two processes:

the 510(k) clearance process, which generally takes from four to 12 months but may take longer; and

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

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

The use of our products and those of our competitors is also affected by federal and state regulations, which provide for regulation of laboratory testing, as well as by the laws and regulations of foreign countries. The scope of these regulations includes quality control, proficiency testing, personnel standards and inspections. In the United States of America, 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 Clinical Laboratory Improvement Amendments. We believe this waived classification is critical for our products to be successful in their markets. Any failure of our new tests to obtain waived status under the Clinical Laboratory Improvement Amendments will severely limit our ability to commercialize such tests. Loss of waived status for existing diagnostic products or failure to obtain waived status for new products could limit our revenue, which would severely harm our business.

***We may 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 could harm our business. We and our contract manufacturers are also subject to federal, state and foreign regulations regarding the manufacture of healthcare products and diagnostic devices, including:

quality system regulations, which requires the maintenance of a quality system consistent with Food and Drug Administration regulations;

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

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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 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 will depend in part on our ability to develop and maintain the proprietary aspects of our technology and operate without infringing the proprietary rights of others. We have nine United States of America patents and have filed patent applications relating to our technology internationally under the Patent Cooperation Treaty and individual foreign patent applications. The risks of relying on the proprietary nature of our technology include:

our pending patent applications may not result in the issuance of any patents, or, if issued, such patents may not offer protection against competitors with similar technology;

our patents may be challenged, invalidated or circumvented in the future, and the rights created under our patents may not provide a competitive advantage;

competitors, many of whom have substantially greater resources than us and have made substantial investments in competing technologies, may seek to apply for and obtain patents covering technologies that are more effective than ours. This could render our technologies or products obsolete or uncompetitive or could prevent, limit or interfere with our ability to make, use or sell our products either in the United States of America 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 of America 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 substantial diversion of attention of technical and management personnel.

In the past, patent infringement claims have been asserted against us. On December 23, 1999, a complaint entitled Roche Diagnostics GmbH v. Health Care Solutions AG, Euromedix N.V./SA and Cholestech Corporation was filed with the Canton Court of the Canton Zug in Zug, Switzerland by Roche Diagnostics seeking a cease and desist order barring us and two of our distributors from distributing HDL assay single-use test cassettes in Switzerland. The complaint alleges that we violated a Roche European patent for HDL. On July 11, 2000, the court denied the plaintiff's request for an injunction and ordered it to pay a portion of our legal fees. On May 2, 2002, in response to our motion, the court ruled that it did not have local jurisdiction over us and ordered the plaintiff to pay our legal fees. There can be no assurance as to whether the plaintiff will appeal this ruling or whether any additional action will be resolved in our favor.

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Additionally, in January 2000, a complaint was filed in the District Court, Dusseldorf, Germany against us and two of our distributors seeking a cease and desist order barring the distributors from shipping HDL single-use test cassettes into Germany. The complaint alleges we and our distributors violated a Roche German priority patent for HDL by selling our single-use test cassette containing a HDL assay. On December 4, 2001, a hearing was held in Dusseldorf, Germany at which Cholestech and Roche witnesses testified. A hearing has been set for September 3, 2002.

In September 2000, we were served a complaint, No. Ei/Ti ROCH 04002, filed in Vienna, Austria by Roche Diagnostics, seeking a cease and desist order barring us and one of our distributors from distributing HDL assay single-use test cassettes in Austria. The complaint alleges that we violated a Roche European patent for HDL. On July 10, 2002, a hearing was held in the District Court in Vienna at which the District Court suspended the infringement suit.

We believe that all of these suits are without merit, that we have not engaged in any wrongdoing and that the outcome of these matters will not result in a material adverse effect. We intend to defend the cases vigorously; however, there can be no assurance that these lawsuits will be resolved in our favor.

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 meaningfully protect our right 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 obtain licenses for new products. We may be unable to obtain licenses for technology patented by others on commercially reasonable terms, or at all. We also may be unable to develop alternative approaches if we are unable to obtain licenses. Also, our future licenses may not be adequate for the operation of our business. Failure to obtain adequate licenses on commercially reasonable terms could prevent us from producing our products and severely harm our business.

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

The markets for diagnostic products and testing services in which we operate are intensely competitive. Our competition consists primarily of clinical and hospital laboratories, as well as manufacturers of bench top analyzers. To achieve and maintain market acceptance for the LDX System and the GDX System, we must demonstrate that the LDX System and the GDX System are attractive alternatives to bench top analyzers as well as to clinical and hospital laboratories. This will require physicians to change their established means of having such tests performed. The LDX System and the GDX System may be unable to compete with these other testing services and analyzers. In addition, companies with a significant presence in the market for therapeutic monitoring, 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

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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.

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

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

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

Sale and use of our products and performance of our testing services 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 and professional liability insurance, 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 hurt our financial condition.

***We may need additional capital in the future to support our growth, and such additional funds may not be available to us***

We intend to expend substantial funds for capital expenditures and working capital related to research and development, expansion of sales and marketing activities and other working capital and general corporate purposes. We also plan to expend significant amounts in further developing our testing services business. Although we believe our cash, cash equivalents, marketable securities, cash flow anticipated to be generated by future operations and available bank borrowings under an existing line of credit will be sufficient to meet our operating requirements for the foreseeable future, we may still require additional financing. For example, we may be required to expend greater than anticipated funds if unforeseen difficulties arise in expanding manufacturing capacity for existing cassettes or in the course of completing required additional development, obtaining necessary regulatory approvals, obtaining waived status under CLIA or introducing or scaling up manufacturing for new tests. Further developing our testing services business may also require more capital than we currently anticipate.

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If we need additional capital in the future, we may seek to raise additional funds through public or private financing, collaborative relationships or other arrangements. Any additional equity financing may be dilutive to our existing shareholders or have rights, preferences and privileges senior to those of our existing shareholders. If we raise additional capital through borrowings, the terms of such borrowings may impose limitations on how our management may operate the business in the future. Collaborative arrangements, if necessary to raise additional funds, may require us to relinquish our rights to technologies, products or marketing territories. Our failure to raise capital on acceptable terms when needed could prevent us from developing our products and our business.

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

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

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

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

quarterly variations in our results of operations;

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;

developments in or disputes regarding patent or other proprietary rights;

stock market price and volume fluctuations, which have particularly affected the market prices for medical products and high technology companies and which are often been unrelated to the operating performance of such companies; and

general economic, political and market conditions.

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.

**Table of Contents****ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK****Quantitative Disclosures**

Our exposure to market risks is inherent in our operations, primarily to interest rates relating to our investment portfolio. We do not use derivative financial instruments in our investment portfolio and had no holdings of derivative financial or commodity instruments as of June 28, 2002.

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

We have concluded that the fair market value of our investment portfolio or related income would not be significantly impacted by changes in interest rates due to the nature of our marketable securities, which do not exceed fiscal year 2004 and have primarily fixed interest rates.

Our policy is to hedge 100% of all committed purchase contracts and a lesser percentage for forecasted purchases. Due to increased committed and forecasted purchases, we entered into additional forward contracts to purchase £425,000 for approximately \$670,000 on July 25, 2002. The new contracts mature at various dates through March 21, 2003.

The following table presents the future principal cash flows or amounts and related weighted average interest rates expected by year for our existing cash and cash equivalents, marketable securities, long-term investments and derivative positions as of June 28, 2002.

	Fiscal Year		Total	Fair Value
	2003	2004		
	(in thousands)			
Cash, cash equivalents	\$ 10,730	\$	\$ 10,730	\$ 10,730
Short-term marketable securities	\$ 8,160	\$ 1,026	\$ 9,186	\$ 9,186
Weighted average interest rate	2.07%	5.80%		
Long-term marketable securities	\$	\$ 4,824	\$ 4,824	\$ 4,824
Weighted average interest rate		5.81%		
Forward currency contracts	\$ 1,091	\$ 68		\$ 1,159

**Qualitative Disclosures**

Our primary interest rate risk exposures relate to:

The available for sale securities will fall in value if market interest rates increase.

The impact of interest rate movements on our ability to obtain adequate debt financing to fund future operations.

We have the ability to hold at least a portion of the fixed income investments until maturity and therefore would not expect the operating results or cash flows to be affected to a significant degree by a sudden change in market interest rates on our short and long term marketable securities portfolio.

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**PART II OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS.**

On December 23, 1999, a complaint entitled Roche Diagnostics GmbH v. Health Care Solutions AG, Euromedix N.V./SA and our company was filed with the Canton Court of the Canton Zug in Zug, Switzerland by Roche Diagnostics seeking a cease and desist order barring us and two of our distributors from distributing HDL assay single-use test cassettes in Switzerland. The complaint alleges that we violated a Roche European patent for HDL. On July 11, 2000, the court denied the plaintiff's request for an injunction and ordered it to pay a portion of our legal fees. On May 2, 2002, in response to our motion, the court ruled that it did not have local jurisdiction over us and ordered the plaintiff to pay our legal fees. There can be no assurance as to whether the plaintiff will appeal this ruling or whether any additional action will be resolved in our favor. At this point in time no schedule has been set regarding additional court activity.

In January 2000, a complaint, No. 4 O 4/00, was filed in the District Court, Dusseldorf, Germany by Roche Diagnostics against us, and two of our distributors, seeking a cease and desist order barring the distributors from shipping HDL single-use test cassettes into Germany. The complaint alleges we, and our distributors, violated a Roche German priority patent for HDL by selling our single-use test cassette containing a HDL assay. On December 4, 2001, a hearing was held in Dusseldorf, Germany at which Cholestech and Roche witnesses testified. A hearing has been set for October 29, 2002. We believe the suit is without merit and intend to defend the case vigorously. However, there can be no assurance that the lawsuit will be resolved in our favor.

On May 8, 2002, Roche Diagnostics extended the patent litigation suit to include an additional party, INCOMAT Medizinische Gerate GmbH. A preliminary hearing was held on July 9, 2002 in District Court, Dusseldorf, Germany. The court has not yet issued its ruling for the hearing.

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

In September 2000, a complaint, No. Ei/Ti ROCH 04002 was filed in Vienna, Austria by Roche Diagnostics, seeking a cease and desist order barring us and one of our distributors from distributing HDL assay single-use test cassettes in Austria. The complaint alleges that we violated a Roche European patent for HDL. On July 10, 2002, a hearing was held in the District Court in Vienna at which the District Court suspended the infringement suit. There can be no assurance as to whether the plaintiff will take any additional action or whether any additional action will be resolved in our favor.

**ITEM 5. OTHER INFORMATION.**

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

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

(a) Exhibits.

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

(b) Reports on Form 8-K.

We did not file any reports on Form 8-K during the thirteen weeks ended June 28, 2002.



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**SIGNATURES**

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

CHOLESTECH CORPORATION

Date: August 9, 2002

/s/ Warren E. Pinckert II

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

Date: August 9, 2002

/s/ William W. Burke

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

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**INDEX TO EXHIBITS**

Exhibit No.	Description
99.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002