CHOLESTECH CORPORATION
Form 10-Q
August 09, 2001
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SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES AND EXCHANGE ACT OF 1934
For the quarterly period ended June 29, 2001

[ ] 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	**94-3065493**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

3347 Investment Boulevard, Hayward, CA 94545
(Address of Principal Executive Offices) (Zip Code)

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

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 [X] No [ ]

As of July 26, 2001, 12,140,366 shares of common stock of the Registrant were outstanding.

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PART I

FINANCIAL INFORMATION

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PART I FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)
(unaudited)

	June 29, 2001	March 30, 2001 (1)
Assets		
Current assets:		
Cash and cash equivalents	$2,866	$4,052
Marketable securities	4,623	4,697
Accounts receivable, net	4,654	3,014
Inventories, net	4,446	3,658
Prepaid expenses and other current assets	764	717
Total current assets	17,353	16,138
Property and equipment, net	8,423	7,777
Long-term investments	3,566	3,616
Goodwill, net	3,143	3,143
Other assets, net	66	68
Total assets	$32,551	$30,742
Liabilities and Shareholders Equity		
Current liabilities:		

Accounts payable and accrued expenses	$4,386	$3,893
Accrued payroll and benefits	1,872	1,900
Other liabilities	116	91
Total current liabilities	6,374	5,884
Contingencies (Note 6)		
Shareholders equity:		
Preferred stock		
Common stock	72,903	72,819
Accumulated other comprehensive income	59	69
Accumulated deficit	(46,785)	(48,030)
Total shareholders equity	26,177	24,858
Total liabilities and shareholders equity	$32,551	$30,742

(1) The information in this column was derived from the Company s audited consolidated financial statements for the fiscal year ended March 30, 2001.

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 29, 2001	June 30, 2000
Revenue:		
Product	$10,356	$7,980
Service	2,022	1,219
Total revenue	12,378	9,199
Cost of revenue:		
Product	4,387	3,334
Service	376	394
Total cost of revenue	4,763	3,728

Gross profit	7,615	5,471
Operating expenses:		
Sales and marketing	3,574	2,250
Research and development	614	896
General and administrative	1,838	1,373
Website and related costs		413
Goodwill amortization		150
Total operating expenses	6,439	4,669
Income from operations	1,176	802
Interest and other income, net	121	188
Income before taxes	1,297	990
Provision for income taxes	52	41
Net income		

$1,245	$949
Net income per share:	
Basic	
$0.10	$0.08
Diluted	
$0.10	$0.08
Shares used to compute net income per share:	
Basic	
12,105	11,976
Diluted	
12,508	12,486

See Notes to Condensed Consolidated Financial Statements

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

	Thirteen weeks ended	
	June 29, 2001	June 30, 2000
Cash flows from operating activities:		
Net income	$1,245	$949
Adjustments to reconcile net income to net cash used in operating activities:		
Depreciation and amortization	618	561
Change in allowance for doubtful accounts	106	14
Changes in assets and liabilities:		
Accounts receivable	(1,746)	(770)
Inventories	(788)	(148)
Prepaid expenses and other assets	(47)	(109)
Accounts payable and accrued expenses	1,348	(302)
Payment of legal settlement		(855)
Accrued payroll and benefits	(28)	(297)
Other liabilities		25
Net cash used in operating activities	(122)	(102)
Cash flows from investing activities:		

Maturities of marketable securities	3,463	1,704
Purchases of marketable securities	(3,349)	(708)
Purchases of property and equipment	(1,262)	(1,670)
Net cash used in investing activities	(1,148)	(674)
Cash flows from financing activities:		
Issuance of common stock	84	46
Net cash provided by financing activities	84	46
Net decrease in cash and cash equivalents	(1,186)	(730)
Cash and cash equivalents at beginning of period	4,052	6,959
Cash and cash equivalents at end of period	$2,866	$6,229

Non-cash financing activities:

Issuance of common stock in exchange for cancellation of liability
$ $300
Additional goodwill accrual relating to purchase of Health Net assets
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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 who do not express an opinion thereon, 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 30, 2001. The condensed consolidated balance sheet as of March 30, 2001 has been derived from, but does not include all the disclosures contained in, the audited consolidated financial statements for the fiscal year ended March 30, 2001. The information furnished includes all adjustments and accruals consisting only of normal recurring accrual adjustments that are, in the opinion of management, necessary for a fair presentation of results for the interim periods. Certain information or footnote disclosure normally included in financial statements prepared in accordance with generally accepted accounting principles has been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission.

The interim results are not necessarily indicative of the results of operations for the full fiscal year ending March 29, 2002.

2. Balance Sheet Data

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

	June 29, 2001	March 30, 2001
Raw materials	$1,527	$1,263
Work-in-process	1,567	1,219
Finished goods	1,352	1,176

$4,446	$3,658

3. Change In Accounting Principle

In July 2001, the Financial Accounting Standards Board issued SFAS No. 142, *Goodwill and Other Intangible Assets*, (SFAS No. 142), which establishes financial accounting and reporting for acquired goodwill and other intangible assets and supersedes APB Opinion No. 17, *Intangible Assets.* It addresses how intangible assets that are acquired individually or with a group of other assets should be accounted for in financial statements upon their acquisition. SFAS No. 142 also addresses how goodwill and other intangible assets should be accounted for after they have been initially recognized in the financial statements.

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Pursuant to SFAS No. 142, goodwill is not required to be amortized as an expense into the results of operations. It is, however, subject to periodic reviews for impairment. A two-step impairment test shall be used to identify potential goodwill impairment and measure the amount of a goodwill impairment loss to be recognized, if any.

The Company has elected to early adopt SFAS No. 142 beginning with the first quarter of fiscal 2002. The Company has reviewed its goodwill for impairment and determined that no impairment loss needs to be recognized. The Company currently has $3.1 million of unamortized goodwill, all of which is in the WellCheck business unit. The Company has no other intangible assets in any of its business units.

The following table reconciles the Company s fiscal 2001 first quarter net income adjusted to exclude goodwill amortization pursuant to SFAS No. 142 to amounts previously reported.

	Thirteen Weeks Ended	
	June 29, 2001	June 30, 2000
Reported net income	$1,245	$949
Add back: Goodwill amortization		
150		
Adjusted net income		
$1,245	$1,099	

Basic EPS:	
Reported net income	$0.10 $0.08
Goodwill amortization	0.01
Adjusted net income	$0.10 $0.09
Diluted EPS:	
Reported net income	$0.10 $0.08
Goodwill amortization	0.01
Adjusted net income	$0.10 $0.09

4. Earnings Per Share

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

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

(In thousands, except per share data)

	Thirteen Weeks Ended June 29, 2001			Thirteen Weeks Ended June 30, 2000 (1)		
	Net Income	Shares	Per Share	Net Income	Shares	Per Share
Basic EPS	$1,245	12,105	$0.10	$949	11,976	$0.08
Effect of dilutive securities						
	403	510				
Diluted EPS						
	$1,245	12,508	$0.10	$949	12,486	$0.08

As of June 29, 2001, options to purchase 1,425,488 shares of common stock were considered anti-dilutive because the respective exercise prices were greater than the average fair market value of the common stock. As of June 30, 2000, options to purchase 328,533 shares of common stock were considered anti-dilutive because the respective exercise prices were greater than the average fair market value of the common.

(1) See Note 3 for adjusted earnings per share data which reflect the adoption of SFAS No. 142.

5. Recent Accounting Pronouncements

In June 1998, the Financial Accounting Standards Board issued SFAS No. 133 *Accounting for Derivative Instruments and Hedging Activities*, (SFAS No. 133), which establishes accounting and reporting standards for derivative instruments and hedging activities. It requires that an entity recognize all derivatives as either assets or liabilities on the balance sheet and measure those instruments at fair value. The Company adopted SFAS No. 133, as required by SFAS No. 137, *Accounting for Derivative Instruments and Hedging Activities Deferral of the Effective Date of the FASB Statement No. 133,* beginning with the first quarter of fiscal 2002. The adoption of SFAS No. 133 had no material impact on financial reporting and related disclosures of the Company.

In July 2001, the Financial Accounting Standards Board issued SFAS No. 141, *Business Combinations*, (SFAS No. 141), which establishes financial accounting and reporting for business combinations and supersedes APB Opinion No. 16, *Business Combinations* and FASB Statement No. 38, *Accounting for Preacquisition Contingencies of Purchased Enterprises.* It requires that all business combinations in the scope of SFAS No. 141 are to be accounted for using one method, the purchase method. The provisions of SFAS No. 141 apply to all business combinations initiated after June 30, 2001, and also apply to all business combinations accounted for using the purchase method for which the date of acquisition is July 1, 2001 or later. The Company adopted SFAS No. 141 beginning with the quarter ended June 29, 2001; such adoption had no impact on the financial reporting and related disclosures of the Company.

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In July 2001, the Financial Accounting Standards Board issued SFAS No. 142 *Goodwill and Other Intangible Assets*, (SFAS No. 142), which establishes financial accounting and reporting for acquired goodwill and other intangible assets and supersedes APB Opinion No. 17, *Intangible Assets.* It addresses how intangible assets that are acquired individually or with a group of other assets should be accounted for in financial statements upon their acquisition, and after they have been initially recognized in the financial statements. The provisions of SFAS No. 142 are effective starting with fiscal years beginning after December 15, 2001. Early adoption is permitted for entities with fiscal years beginning after March 15, 2001, provided that the first interim financial statements have not previously been issued. Accordingly, the Company has elected to early adopt SFAS No. 142 beginning with the quarter ended June 29, 2001 and has disclosed the impact of such adoption in Note 3 to the condensed consolidated financial statements.

6. Contingencies

On February 5, 1999, a complaint entitled Ree v. Pinckert, et al., No. C99-0562 (PJH) was filed in the United States District Court for the Northern District of California. The action was a putative class action and the complaint alleged that the Company and certain of its current and former officers violated the federal securities laws by making false and misleading statements concerning the Company and its business during the period of June 28, 1996 through June 25, 1998. On June 14, 2001, the Company executed an agreement in principle

with plaintiffs to resolve this matter for a payment $3.0 million by its insurance carrier. The Company recorded a $1.3 million charge during the fiscal year ended March 30, 2001 for legal fees and insurance costs related to resolving this matter. The Company paid $855,000 to its insurance company and $121,000 for legal fees in the quarter ended June 29, 2001. The settlement is still contingent on court approval.

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. Segment Information

During fiscal 2000, the Company launched two new business units, WellCheck and WellCheck.com. As a result, the Company operated in three reportable segments: Diagnostic Products, WellCheck and WellCheck.com. The Company has determined that starting in fiscal 2002, WellCheck and WellCheck.com will operate and be managed as one segment. All operating results will present the combined results for WellCheck and WellCheck.com as a single segment, and as a result, all prior year activity has been combined to reflect the change. The Company s wholly-owned subsidiary, WellCheck.com, was legally merged into its wholly-owned subsidiary, WellCheck, effective June 22, 2001. For fiscal 2002, the two resulting segments are strategic business units that offer different products, and as a result, are managed separately. The accounting policies of the segments are the same. Segment data excludes all corporate-headquarters costs as they are not allocated to the operating segments, and inter-segment

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revenue is eliminated. Asset information by segment has not been presented as the Company does not produce such information.

Results for the thirteen weeks ended June 29, 2001 and June 30, 2000 by segment are as follows (in thousands):

	Diagnostic Products		WellCheck		Inter-Company		Total	
	2001	2000	2001	2000	2001	2000	2001	2000
Net revenue	$10,356	$7,980	$2,507	$1,583	$(485)	$(364)	$12,378	$9,199
Cost of revenue	4,387	3,334	861	758	(485)	(364)	4,763	3,728
Gross profit	5,969	4,646	1,646	825			7,615	5,471

Operating expenses:

Sales and marketing
2,382 1,769 1,100 465 3,482 2,234
Research and development
614 505 391 614 896
General and Administrative
212 204 391 239 603 443
Web site and related costs
413 413
Goodwill amortization and other
150 150

Total operating expenses
3,208 2,478 1,904 1,245 5,112 3,723

Income (loss) from operations
$2,761 $2,168 $(258) $(420) $ $ $2,503 $1,748

Reconciliation of segment profit to the Company s consolidated totals:

	2001	2000
Total income from operations for reportable segments	$2,503	$1,748
Unallocated corporate expenses	(1,327)	(946)
Interest income	121	188
Provision for income taxes	(52)	(41)
Net income	$1,245	$949

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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 , poten 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.

You should read the following discussion and analysis in conjunction with our financial statements and the related notes thereto included in this Quarterly Report on Form 10-Q.

General

We operate in two business segments:

Diagnostic Products develops, manufactures and markets our Cholestech L D X ® System (the L D X System) which performs near-patient diagnostic testing to assist in assessing for risk of heart disease, diabetes, certain liver diseases, and in the monitoring of therapy to treat those diseases.

WellCheck conducts consumer testing within the United States that assesses the risk of heart disease and other diseases and assists in the monitoring of therapy to treat those diseases.

The Company determined that starting in fiscal 2002, WellCheck and WellCheck.com would be operated and be managed as one segment. All operating results present the combined results for WellCheck and WellCheck.com as a single segment, and as a result, all prior year activity has been combined to reflect the change.

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Diagnostic Products currently manufactures and markets the L D X System, including the L D X Analyzer and a variety of single-use test cassettes, in the United States and internationally. The L D X System allows health care 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.

WellCheck currently provides cholesterol and related testing services and education to the general public using the L D X System. This testing creates 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 Test Event Activity Management Software (TEAMS) technology which automates registration, data acquisition and information management at promotional, corporate wellness and other consumer testing events and provides consumers with a personalized risk assessment for heart disease. 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, corporate wellness, retail markets and other convenient venues which broaden consumer access to testing while assisting consumer product companies, such as pharmaceutical companies, in customer acquisition. Our goal is to develop the first nationwide consumer testing services company for

chronic diseases.

The ongoing investment relating to WellCheck may result in negative cash flows for us. The development and commercialization of new software and testing programs will require sales, marketing, development and other expenditures. The amount of expenditures and timing will have an impact on our ability to maintain profitability and positive cash flows.

WellCheck s revenue will fluctuate as sponsorships progress. As companies other than pharmaceutical firms become sponsors and programs mature, the number of test sites and the number of tests will vary. 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.

Result of Operations

Thirteen weeks ended June 29, 2001 and June 30, 2000

Revenue. During the thirteen weeks ended June 29, 2001, revenue increased 35% to $12.4 million from $9.2 million for the thirteen weeks ended June 30, 2000. Diagnostic Products represented 84% and 87% of our revenue for the first quarter of fiscal 2001 and 2000, respectively. During the quarter ended June 29, 2001 and June 30, 2000, WellCheck represented 16% and 13% of our revenue, respectively, after inter-company eliminations.

International revenue increased by 86% from $1.4 million to $2.6 million for the thirteen weeks ended June 29, 2001, compared to the same period in fiscal 2000. Our Diagnostic Products segment generated all the international revenue.

Segment performance was as follows:

Diagnostic Products revenue increased $2.4 million, or 30%, from $8.0 million for the thirteen weeks ended June 30, 2000 to $10.4 million for the thirteen weeks ended June 29, 2001. The majority of the increase related to a $1.7 million or 26% improvement in sales of single use test cassettes. Additionally, sales of L D X Analyzers were $463,000 or 49% higher over the comparable prior year period.

WellCheck revenue increased $924,000 or 58% to $2.5 million, before inter-company eliminations, for the quarter ended June 29, 2001, compared to $1.6 million for the quarter ended June 30, 2000 before inter-company eliminations. The majority of the increase related to contracts with a single sponsor who accounted for 84% of WellCheck s revenue in fiscal 2001.

Cost of Revenue. Cost of revenue increased 30% to $4.8 million for the thirteen weeks ended June 29, 2001, from $3.7 million for the thirteen weeks ended June 30, 2000. Gross margins were 62% and 59% for the quarter ended June 29, 2001, and June 30, 2000, respectively. Diagnostic Products accounted for 92% and WellCheck accounted for 8% of the cost of revenue after inter-company eliminations for the thirteen weeks ended June 29, 2001. For the thirteen weeks ended June 30, 2000, Diagnostic Products accounted for 89% and WellCheck accounted for 11% 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 increased $1.1 million, driven by a 30% increase in sales, to $4.4 million for the thirteen weeks ended June 29, 2001, from $3.3 million for the thirteen weeks ended June 30, 2000. Gross margin remained constant at 58% of total revenue for the quarters ended June 29, 2001 and June 30, 2000, respectively. The increase in cost of revenue was the result of higher indirect labor staffing, depreciation for facilities modifications, new equipment and increased material consumption. The validation of a new production line generated additional costs that will cease once the equipment is fully functional.

WellCheck cost of revenue includes travel expenses, 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. For the quarter ended June 29, 2001, total cost of revenue was $861,000 or 34% of revenue before inter-company eliminations, compared to $758,000 or 48% of revenue before inter-company eliminations for the quarter ended June 30, 2000. The reduction in percentage of revenue was related to certain travel costs that were an expense in the prior year but were paid directly by the customer during the

current quarter.

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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 WellCheck Associates who perform consumer testing. Sales and marketing expenses increased 57%, or $1.3 million, to $3.6 million for the thirteen weeks ended June 29, 2001, from $2.3 million for the thirteen weeks ended June 30, 2000. Sales and marketing expense increased to 29% of revenue for the first quarter of fiscal 2001 from 24% of revenue for the first quarter of fiscal 2000. Diagnostic Products accounted for 67%, WellCheck accounted for 31% and unallocated corporate amounts accounted for 2% of sales and marketing expense for the thirteen weeks ended June 29, 2001. For the thirteen weeks ended June 30, 2000, Diagnostic Products accounted for 78%, WellCheck accounted for 21% and unallocated corporate amounts accounted for 1% of the total sales and marketing expense.

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

Diagnostic Products sales and marketing expenses increased 33% to $2.4 million for the thirteen weeks ended June 29, 2001, from $1.8 million for the thirteen weeks ended June 30, 2000. Sales and marketing expenses increased to 23% of revenue for the thirteen weeks ended June 29, 2001, from 22% in the comparable period for fiscal 2000. The increase can be attributed to increased wages and related costs, commissions, public relations, advertising and distributor relations. Much of the increase in public relations and advertising was related to the launch of our ALT (liver function) product, the only ALT test waived under the Clinical Laboratory Improvement Act of 1976 (CLIA).

WellCheck sales and marketing expenses were $1.1 million or 44% of revenue for the quarter ended June 29, 2001, compared to $465,000 or 29% of revenue for the quarter ended June 30, 2000. Most of the increased spending can be attributed to wages and other headcount related expense to support the increased service revenue.

Research and Development Expenses. Research and development expenses include salaries, bonuses, outside services, supplies and depreciation of capital equipment. Research and development expenses decreased 31% to $614,000 for the quarter ended June 29, 2001, from $896,000 for the quarter ended June 30, 2000. Research and development expenses as a percentage of revenue decreased to 5% for the thirteen weeks ended June 29, 2001, from 10% for the thirteen weeks ended June 30, 2000. The Diagnostic Products business unit represented 100% and 56% of our research and development expenses for the thirteen weeks ended June 29, 2001 and June 30, 2000, respectively. WellCheck accounted for 44% of the research and development expenses during the quarter ended June 30, 2000.

Research and development expenses in each of our segments were as follows:

Diagnostic Products research and development expenses increased by $109,000 or 22% for the quarter ended June 29, 2001, to $614,000 compared to $505,000 in the comparable period ended June 30, 2000. Increased headcount during fiscal 2002 from the corresponding quarter of fiscal 2001 was the primary cause for the increased expenses that resulted in additional wage and related costs.

WellCheck incurred no research and development expenses in the thirteen weeks ended June 29, 2001. During the thirteen weeks ended June 29, 2000, research and

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development expenses were $391,000 or 25% of revenue. These costs related to the development and validation of the TEAMS software and WellCheck.com which was launched at the end of the first quarter of fiscal 2001.

Website and Related Costs. Website and related costs include depreciation of the TEAMS software, compensation and benefits, software maintenance, web hosting, content and other outside services relating to the operation of TEAMS software and Wellcheck.com. For the thirteen weeks ended June 29, 2001, website and related costs were $413,000 or 3% of revenue. The majority of these costs related to TEAMS software and support, and all costs were attributable to the WellCheck segment.

General and Administrative Expenses. General and administrative expenses include compensation, benefits and expenses for outside professional services including information services, legal and accounting. General and administrative expenses increased 29% to $1.8 million for the thirteen weeks ended June 29, 2001, from $1.4 million for the thirteen weeks ended June 30, 2000. General and administrative expenses remained constant at 15% of revenue for the thirteen weeks ended June 29, 2001 and for the thirteen weeks ended June 30, 2000. The Diagnostic Products business unit represented 12%, WellCheck represented 21% and unallocated corporate expenses represented 67% of our general and administrative expenses for the thirteen weeks ended June 29, 2001. Diagnostic Products accounted for 15%, WellCheck accounted for 17% and unallocated corporate expenses accounted for 68% of the general and administrative expenses for the first quarter of fiscal 2001.

Corporate general and administrative expenses increased by 29% to $1.2 million for the thirteen weeks ended June 29, 2001 from $930,000 for the thirteen weeks ended June 30, 2000. The increase was attributed to severance expense for our former chief financial officer, wages and other related costs relating to increased headcount and shared expenses for facilities, human resources and information services.

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

Diagnostic Products general and administrative expenses increased by 4% to $212,000 for the thirteen weeks ended June 29, 2001 from $204,000 for the thirteen weeks ended June 30, 2000. The increase was the result of increased wages, travel and other staff related costs.

WellCheck general and administrative expenses increased by $152,000 or 64% to $391,000 for the thirteen weeks ended June 29, 2001 from $239,000 for the thirteen weeks ended June 30, 2000. The majority of the increase related to a severance expense for this business segment s chief operating officer.

Goodwill amortization. As the result of our early adoption of SFAS No. 142, there was no goodwill amortization for the quarter ended June 29, 2001 compared to $150,000 or 2% of revenue for the quarter ended June 30, 2000. The fiscal 2001 first quarter goodwill amortization related exclusively to the amortization of goodwill incurred upon the acquisition of Health Net, Inc. in January 2000. Health Net became the foundation for our WellCheck business.

Interest and other income, net. Interest and other income, net, reflects income from the investment of cash balances and marketable securities. Interest income decreased by 36% to

$121,000 for the thirteen weeks ended June 29, 2001 from $188,000 for the thirteen weeks ended June 30, 2000. The decrease was the result of lower investment balances in marketable securities and decreased yields on such investments.

Income Taxes. The provision for income taxes increased 27% to $52,000 for the thirteen weeks ended June 29, 2001 from $41,000 for the thirteen weeks ended June 30, 2000. Since we have significant tax credit carryforwards, the provision for income taxes for the quarter ended June 29, 2001 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 fiscal 2002. Our estimated effective tax rate is expected to remain below the federal statutory rate throughout fiscal 2002.

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 29, 2001, we raised $72.9 million in net proceeds from equity financings. As of June 29, 2001, we had $11.1 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. 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 0.5% below the bank s prime rate. The line of credit agreement expires on May 1, 2002. As of June 29, 2001, there were no borrowings outstanding under the line of credit.

During the first thirteen weeks of fiscal 2002, we used $122,000 of cash from operating activities compared to $102,000 of cash used in the first thirteen weeks of fiscal 2001. The cash used in operations for the first quarter of fiscal 2001 was comprised of net income of $1.2 million and adjustments for non-cash items including $724,000 for depreciation and amortization 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 combined $1.7 million increase in

accounts receivable and a $788,000 increase in inventory. Also, the payment of $855,000 for accrued legal and other related expenses related to the settlement of our class action lawsuit further consumed cash. For the comparable quarter of fiscal 2001, cash used was comprised of net income of $949,000 plus adjustments for non-cash items, including $575,000 of depreciation and provision for doubtful accounts. This was offset by a combined $1.0 million increase in accounts receivable, inventory and prepaid expenses and a combined $599,000 decrease in accrued payables and payroll liabilities.

Net cash used in investing activities was $1.1 million in the first thirteen weeks of fiscal 2002, consisting primarily of additional production and facility equipment costs of $1.3 million. Conversely, there was a net sale of $114,000 in marketable securities. For the first thirteen weeks of fiscal 2001, we purchased $1.7 million of capital equipment and had a net sale of $1.0 million of marketable securities.

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Proceeds from our stock option exercises and stock purchase programs provided $84,000 in the first thirteen weeks of fiscal 2002. For the corresponding thirteen weeks of fiscal 2001, $46,000 was provided by exercises of options pursuant to our stock incentive and stock purchase programs.

During the remainder of fiscal 2002, we intend to expend approximately $2.9 million for capital purchases related to expansion of our information technology systems, expansion of our manufacturing capacity and research and development. As of June 29, 2001, however, contracts have not been signed and schedules have not been set.

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 startup costs for WellCheck, facilities modification or expansion, obtaining necessary product regulatory approvals, or scaling up manufacturing for new tests.

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 successes 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 of our technologies, 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 Potential Factors Affecting Future Operating Results.

Recent Accounting Pronouncements

In June 1998, the Financial Accounting Standards Board issued SFAS No. 133 *Accounting for Derivative Instruments and Hedging Activities*, (SFAS No. 133), which establishes accounting and reporting standards for derivative instruments and hedging activities. It requires that an entity recognize all derivatives as either assets or liabilities on the balance sheet and measure those instruments at fair value. The Company adopted SFAS No. 133, as required by SFAS 137 *Accounting for Derivative Instruments and Hedging Activities Deferral of the*

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Effective Date of the FASB Statement No. 133, beginning with the first quarter of fiscal 2002. The adoption of SFAS No. 133 had no material impact on financial reporting and related disclosures of the Company.

In July 2001, the Financial Accounting Standards Board issued SFAS No. 141, *Business Combinations*, (SFAS No. 141), which establishes financial accounting and reporting for business combinations and supersedes APB Opinion No. 16, *Business Combinations* and FASB Statement No. 38, *Accounting for Preacquisition Contingencies of Purchased Enterprises.* It requires that all business combinations in the scope of SFAS No. 141 are to be accounted for using one method, the purchase method. The provisions of SFAS No. 141 apply to all business combinations initiated after June 30, 2001, and also apply to all business combinations accounted for using the purchase method for which the date of acquisition is July 1, 2001 or later. We adopted SFAS No. 141 beginning with the first quarter of fiscal 2002, and such adoption of SFAS No. 141 had no impact on our financial reporting and related disclosures.

In July 2001, the Financial Accounting Standards Board issued SFAS No. 142 *Goodwill and Other Intangible Assets,* (SFAS No. 142), which establishes financial accounting and reporting for acquired goodwill and other intangible assets and supersedes APB Opinion No. 17, *Intangible Assets.* SFAS No. 142 addresses how intangible assets that are acquired individually or with a group of other assets should be accounted for in financial statements upon their acquisition, and after they have been initially recognized in the financial statements. The provisions of SFAS No. 142 are effective starting with fiscal years beginning after December 15, 2001. Early adoption is permitted for entities with fiscal years beginning after March 15, 2001, provided that the first interim financial statements have not previously been issued. Accordingly, we have elected to early adopt SFAS No.142 beginning with the quarter ended June 29, 2001 and have disclosed the impact of such adoption in Note 3 to the condensed consolidated financial statements.

Potential Factors Affecting Future Operating Results

We have no prior experience in the testing services business, and if this new business is not successful, we will be greatly harmed.

The testing services business being pursued by our WellCheck business unit is still new to us and to our management team. This will make it more difficult for us to successfully develop this new business. Also, we will be devoting significant resources to developing this new business. If we are not successful in developing this new business, our Diagnostic Products business will be harmed. Even if we are successful at developing the new business, the demands of attempting to grow this new 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 new WellCheck business requires us to operate in

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multiple geographically dispersed locations and adapt our management and financial systems and controls to this new geographically dispersed business. If we cannot successfully manage our geographic expansion, the testing services business will not succeed and we will not recover our investment in the testing services business. As a result, our business would suffer.

Our new testing services business requires significant management attention and financial resources to develop and if this new business is not successful, our business will suffer.

The continued development of our new 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 start-up expenses. The required additional capital may not be available to us at favorable or acceptable terms when required, or at all. If we cannot obtain required additional capital, we may have to change our business strategy, which would be disruptive to our business. 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. If we raise additional capital by issuing equity, this may result in a dilution of existing shareholders interests in us. Also, equity issued by us may have rights, preferences or privileges senior to those of our existing shareholders.

Our L D X System has 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 L D X System, including the L D X Analyzer (our only product platform) and single-use test cassettes, will continue to account for substantially all of the revenue of our Diagnostics Products business for the foreseeable future. If this revenue does not grow, our overall business will be severely harmed. For us to increase revenue, sustain profitability and maintain positive cash flows from operations, the L D X System must continue to gain broader market acceptance among health care providers, particularly physician office laboratories. We have made only limited sales to physician office laboratories to date relative to the size of the available markets. Factors that could prevent broad market acceptance of the L D X System include:

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

The L D X System s accuracy, ease of use, rapid test time, reliability and cost effectiveness compared to 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

Limited availability and amount of reimbursement for performing tests on the L D X System.

If we do not achieve broader market acceptance, our Diagnostic Products business will not grow. Even if we are successful in continuing to place L D X Analyzers at physician office laboratories and other near-patient testing sites, there can be no assurance that placement of

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L D X Analyzers 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. If the Diagnostic Products business does not grow, the new business will not succeed. These results would cause severe financial harm to us.

As a result of these many hurdles to achieving broad market acceptance for the L D X System, demand for the L D X System may not be sufficient to sustain revenue and profits from operations. Because the L D X System currently contributes the vast majority of our revenue, we could be required to cease operations if the L D X System does 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 29, 2001, we had an accumulated deficit of $46.8 million. Our first profitable quarter was the second quarter of fiscal 1998, and our first profitable year was fiscal 1998. We recorded a net loss of $2.6 million for fiscal 2001. For the quarter ended June 29, 2001, we recorded a net profit of $1.2 million. Our profitability and positive cash flows from operations in the future will require:

Broadening market acceptance of our existing product offerings;

Successfully developing, introducing and marketing additional test cassettes or other products for our Diagnostic Products business; and

Successfully developing our new testing services business.

We may experience significant fluctuations in revenue and results of operations on a quarter to quarter basis in the future.

Our quarterly operating results may fluctuate due to numerous factors, including:

The timing and amount of expenditures required for the continued development of our new testing services business;

The timing and level of market acceptance of the L D X System;

The timing of the introduction and availability of new tests;

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

The timing and level of expenditures associated with expansion of sales and marketing activities and overall operations;

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;

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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 results of operations. 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 made 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, our business will be harmed.

Most of our revenue comes from our Diagnostics Products business. We anticipate this will continue for the near term. We also rely on revenue from the Diagnostics Products business to fund the development of our new testing services business. We believe our Diagnostic Products business will not grow significantly if we do not develop new tests to use with the L D X System. If new tests 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. For example, regulatory clearance or approval of any new tests 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 United States Food and Drug Administration 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.

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We face risks from failures in our manufacturing processes.

We internally manufacture all of the single-use test cassettes that are used with the L D X 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 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 employees 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

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 rely on a continuous power supply to conduct our operations, and California s current energy crisis could disrupt our operations and increase our expenses.

California is in the midst of an energy crisis that could disrupt our operations and increase our expenses. In the event of an acute power shortage (i.e. when power reserves for the State of California fall below 1.5%), California has on some occasions implemented, and may in the future continue to implement, rolling blackouts throughout California. We currently have backup generators to maintain only a limited amount of power and are currently in the process of bringing on a building generator in the event of a prolonged blackout. Our current insurance does not provide coverage for any damages we or our customers may suffer as a result of any interruption in our power supply. If blackouts interrupt our power supply, we would be temporarily unable to continue operations at our facilities. Any such interruption in our ability to continue operations at our facilities could damage our reputation, harm our ability to retain existing customers and to obtain new customers and could result in lost revenue, any of which could substantially harm our business and results of operations.

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

We believe we will be required to reduce manufacturing costs for new and existing test cassettes to achieve sustained profitability. We currently operate two manufacturing lines for dry chemistry cassettes. We are installing and validating a third manufacturing line that is currently in pre-production validation and should be operational in August 2001. 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 prolonged period. Also, we may need to implement additional cassette manufacturing cost reduction programs. Failure to implement 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 implement 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 subassemblies, components and raw materials used in the manufacture of our products. Any supply interruption in a single source subassembly, component or raw material could restrict our ability to manufacture 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 could prevent us from manufacturing 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 a raw material, either unknown to us or incompatible with our manufacturing process, could interfere with our ability to manufacture 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 subassemblies, components or raw 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 L D X System, we will be required to expand our operations, particularly in the areas of sales, marketing and manufacturing. As we expand our operations, this expansion will likely result in new and increased responsibilities for management personnel and place significant strain on our management, operating and financial systems and resources. To accommodate any such growth and compete effectively, we will be required to implement and improve our information systems, procedures and controls, and to expand, train, motivate and manage our work force. Our personnel, systems, procedures and controls may not be adequate to support our future operations. Any failure to implement and improve operational, financial and management systems or to manage our work force as required by future growth, if any, could harm our business and prevent us from improving our financial condition as a result of increased sales.

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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 L D X 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 not be able 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 have experienced periods in which sales to some of our major customers, as a percentage of total revenue, have fluctuated due to delays or failures to place expected orders. We expect that sales to a limited number of customers will continue to account for a substantial portion of our total revenue in future periods. In fiscal 2000, Physician Sales and Service, Inc. accounted for approximately 16.9 % of our total revenue and GMR Marketing, Inc. (GMR) accounted for less than 1% of our total revenue. In fiscal 2001, Physician Sales and Service, Inc. accounted for approximately 16.4% of our total revenue and GMR accounted for approximately 7.4% of our total revenue. We do not have long-term agreements with any of our customers. Customers 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, healthcare providers that purchase products such as the L D X 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 not be able 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 will likely fail.

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

Third party payors 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 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 undergoes fundamental change, these changes may harm our business.

We believe that the healthcare industry in the United States is likely to undergo fundamental changes due to current political, economic and regulatory influences. We anticipate that Congress, state legislatures and the private sector will continue to review and assess alternative healthcare delivery and payment systems. Potential alternatives include mandated basic healthcare benefits, controls on healthcare spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spended, 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 health care 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 could be damaging to our business.

The manufacture and sale of our diagnostic products, including the L D X System, is subject to extensive regulation by numerous governmental authorities, principally the Food and Drug Administration and corresponding state and foreign regulatory agencies. We are not

able to commence marketing or commercial sales in the United States of any of the new tests we develop until we receive the required clearances and approvals. The process of obtaining required regulatory clearances and approvals is lengthy, expensive and uncertain. As a result, our new tests under development, even if successfully developed, may never obtain such clearance or

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approval. Additionally, certain material changes to products that have already been cleared or approved are subject to further review and clearance or approval. Medical devices are subject to continual review, and later discovery of previously unknown problems with a cleared product may result in restrictions on the product s marketing or withdrawal of the product from the market. If we lose previously obtained clearances, or fail to comply with existing or future regulatory requirements, we may not be able 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 L D X System. Regulatory changes could hurt our business by increasing burdens on our products or by reducing or eliminating certain competitive advantages of the L D X 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 twelve months but may take longer; and
- The pre-market approval process, which is a longer and more costly process than a 510(k) clearance process, involves the submission of extensive supporting data and clinical information and generally takes one to three years but may take significantly longer.

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

The use of our products and those of our competitors is also affected by federal and state regulations, which provide for regulation of laboratory testing, as well as by the laws and regulations of foreign countries. The scope of these regulations includes quality control, proficiency testing, personnel standards and inspections. In the United States, clinical laboratory testing is regulated under the Clinical Laboratory Improvement Act of 1976. The L D X Analyzer, our total cholesterol, high density lipoproteins, triglycerides and glucose tests in any combination and our ALT test cassette have been classified as waived from the application of many of the requirements under the Clinical Laboratory Improvement Act. 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 Act 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 sales and 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

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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

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

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

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

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

The medical products industry has been characterized by extensive litigation regarding patents and other intellectual property rights; and

An adverse determination in litigation or interference proceedings to which we may become a party could subject us to significant liabilities to third parties or require us to seek licenses from third parties, which may not be available on commercially reasonable terms or at all.

We may in the future become subject to patent infringement claims and litigation or interference proceedings conducted in the United States Patent and Trademark Office to determine the priority of 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. In December 1999, an injunction was filed in Zug, Switzerland by Roche Diagnostics, a subsidiary of Roche Holdings, Ltd., 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. The court is expected to reach a decision on the merits of the complaint in the next several months. 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. The court has requested additional information be submitted by both parties, but has not made any ruling or set additional court dates. 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. At this point, no schedule has been set regarding court activity. We believe all suits are without merit and intend to defend the cases vigorously. We do not believe that we engaged in any wrongdoing and that the outcome of this matter will not result in a material adverse effect; however, there can be no assurance

that the 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 not be able 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 which 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 not be able to obtain licenses for technology patented by others on commercially reasonable terms, or at all. We also may not be able 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.

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We may not be able 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 mainly of clinical and hospital laboratories, as well as manufacturers of bench top analyzers. To achieve market acceptance for the L D X System, we must demonstrate that the L D X System is an attractive alternative 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 L D X System may not be able to compete with these other testing services and analyzers. In addition, companies having a significant presence in the market for therapeutic monitoring, such as Abbott Laboratories, Beckman Coulter, Inc. and Roche Diagnostics (a subsidiary of Roche Holdings, Ltd.), have developed or are developing analyzers designed for near-patient testing. These competitors have substantially greater financial, technical, research and other resources and larger, more established marketing, sales, distribution and service organizations than us. These competitors also offer broader product lines than us, have greater name recognition than us and offer discounts as a competitive tactic. In addition, several smaller companies are currently making or developing products that compete or will compete with ours. We may not have the financial resources, technical expertise or marketing, distribution or support capabilities to compete successfully in the future. Even if we do have such resources and capabilities, we may not employ them successfully.

Failure to retain our key personnel and attract additional qualified Associates could hurt our operations.

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 attract and retain additional highly qualified personnel in those areas. Competition for qualified personnel is intense, particularly in the San Francisco Bay Area where we are located, because of the number of attractive technology employment opportunities and the extremely high cost of living. We may not be able to retain our key personnel or attract or retain other necessary highly qualified personnel in the future. If we do not keep our key personnel or attract other needed Associates, we will not be able to grow our business.

Sale of our diagnostic products and performance of our testing services may subject us to liability claims, and if our insurance is insufficient, this liability could severely harm our business.

Sale of our products and performance of our testing services entail risk of product and professional claims. 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.

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We currently maintain product liability and professional liability and 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 product liability insurance may not be able to be maintained in the future on acceptable terms, 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 related to expansion of our manufacturing capacity, research and development, expansion of sales and marketing activities and other working capital and general corporate purposes. Also, we plan to expend significant amounts in developing our new 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. Developing our new testing services business may also require more capital than we currently anticipate. This possibility is increased given our lack of experience in the markets addressed by this new business.

If additional financing is needed, 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 shareholders and debt financing, if available, may involve restrictive covenants. 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

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offer conditioned on the negation, 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. Factors that cause our stock price to fluctuate include:

- Quarterly variations in our operating results;

Announcements by us and our competitors of technological innovations or new commercial products;

Government regulation;

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.

In the past, following periods of volatility in the market price of a company s stock, securities class action suits have been filed against the issuing company. This type of litigation has been brought against us in the past and could be brought against us in the future, which would result in substantial costs and a diversion of management s attention and resources. Any adverse determination in such litigation could also subject us to significant liabilities.

If third party sponsorship of our testing services business is eliminated or reduced, our revenue will be greatly reduced and our business may fail.

WellCheck derives the majority of its revenue from third parties using our testing services to promote their products. If the third parties decline to participate in the future or the amount of sponsorship is reduced, consumers will be much less likely to use our testing services and our revenue will be greatly reduced and our business will likely fail. Our WellCheck segment has a contract with GMR which is in effect until January 2002, but can be cancelled with a thirty day notice.

If we are unable to expand third-party sponsorship of our testing business, our business will be greatly harmed.

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. WellCheck currently has a contract with GMR which accounts for a significant portion of its testing revenue.

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

We may use acquisitions of existing testing services businesses as a significant part of the development of our new testing business. These acquisitions could be very costly, could result in dilution to existing investors and could result in integration problems that harm the business as a whole. Any acquisition could result in expended significant amounts of cash, issuing potentially dilutive equity securities or incurring debt or amortization expenses related to goodwill and other intangible assets. 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. These difficulties could result in additional expenses and in diversion of management attention, which could prevent the new business from being successful. Any of these results could harm us financially.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Quantitative Disclosures

Our exposure to market risks is inherent in our operations, primarily to interest rates relating to our investment portfolio. We do not use derivative financial instruments in our investment portfolio and had no holdings of derivative financial or commodity instruments as of June 29, 2001.

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 2003 and have primarily fixed interest rates.

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 and long-term investments.

	2002	2003	Total	Fair Value
		(in thousands)		
Cash, cash equivalents	$2,866	$	$2,866	$2,866
Short-term marketable securities	$4,623	$4,623	$4,623	
Weighted average interest rate	5.41%			
Long-term marketable securities	$	$3,566	$3,566	$3,566
Weighted average interest rate		5.83%		

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 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 February 5, 1999, a complaint entitled Ree v. Pinckert, et al., No. C99-0562 (PJH) was filed in the United States District Court for the Northern District of California. The action is a putative class action and the complaint alleges that our company and certain of its current and former officers violated the federal securities laws by making false and misleading statements concerning our company and its business during the period of June 28, 1996 through June 25, 1998. On June 14, 2001, we executed an agreement in principle with plaintiffs to resolve this matter for a payment of $3.0 million by our insurance carrier. We recorded a $1.3 million charge during the year ended March 30, 2001 for legal

fees and insurance costs related to resolving this matter. The Company paid $855,000 to its insurance company and $121,000 for legal fees in the quarter ended June 29, 2001. The settlement is contingent on court approval.

On December 23, 1999, a complaint requesting an injunction, No. ES-580-199, was filed 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. We have filed our response to the complaint. On July 11, 2000, the court denied the plaintiff s request for an injunction and ordered them to pay a portion of our legal fees. The plaintiff has appealed the court ruling. At this point in time no schedule has been set regarding additional court activity. There can be no assurance as to whether the plaintiff will take any additional action, or any additional action will be resolved in our favor.

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. The court has requested additional information be submitted by both parties, but has not made any ruling or set additional court dates. We believe the suit is without merit and intend to defend the case vigorously. Therefore, we do not believe that the outcome of this matter will result in a material adverse effect. However, there can be no assurance that the lawsuit will be resolved in our favor.

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. At this point, no schedule has been set regarding court activity. 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.

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

(a) Exhibits.

None.

(b) Reports on Form 8-K.

We did not file any reports on Form 8-K during the thirteen weeks ended June 29, 2001.

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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, 2001 /s/ Warren E. Pinckert II

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

Date: August 9, 2001

/s/ William W. Burke

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