

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

CHOLESTECH CORPORATION

Form 10-Q

February 07, 2001

1

=====

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended December 29, 2000

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

For the transition period from _____ to _____

Commission file number: 000-20198

CHOLESTECH CORPORATION
(Exact name of registrant as specified in its charter)

CALIFORNIA
(State or other jurisdiction of incorporation or organization)

94-3065493
(I.R.S. Employer Identification 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 No

At January 26, 2001, 12,098,745 shares of common stock of the Registrant were outstanding.

2

CHOLESTECH CORPORATION

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

PART I

FINANCIAL INFORMATION

	Page ----
ITEM 1. FINANCIAL STATEMENTS.	
Condensed Consolidated Balance Sheets	3
Condensed Consolidated Statements of Operations	4
Condensed Consolidated Statements of Cash Flows	5
Notes to Condensed Consolidated Financial Statements	6
ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.	12
ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	36

PART II

OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS	37
ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K.	39
SIGNATURES	40

2

3

CHOLESTECH CORPORATION

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CONDENSED CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS)
(UNAUDITED)

	December 29, 2000 -----	March 31, 2000 (1) -----
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 4,444	\$ 6,959
Restricted cash	1,000	1,000
Marketable securities	4,733	2,850
Accounts receivable, net	2,253	1,839
Inventories	4,006	3,714

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

Prepaid expenses and other current assets	875	902
	-----	-----
Total current assets	17,311	17,264
Property and equipment, net	10,059	8,309
Long-term investments	2,520	3,932
Goodwill	3,325	2,661
Other assets, net	48	52
	-----	-----
Total assets	\$ 33,263	\$ 32,218
	=====	=====
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$ 3,555	\$ 3,788
Accrued payroll and benefits	1,869	1,563
Product warranty	91	91
Other liabilities	--	300
	-----	-----
Total current liabilities	5,515	5,742
	-----	-----
Contingencies (Note 6)		
Shareholders' equity:		
Preferred stock	--	--
Common stock	72,722	71,959
Accumulated other comprehensive income (loss)	23	(59)
Accumulated deficit	(44,997)	(45,424)
	-----	-----
Total shareholders' equity	27,748	26,476
	-----	-----
Total liabilities and shareholders' equity	\$ 33,263	\$ 32,218
	=====	=====

(1) The information in this column was derived from the Company's audited consolidated financial statements for the fiscal year ended March 31, 2000.

See Notes to Condensed Consolidated Financial Statements

3

4

CHOLESTECH CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)
(UNAUDITED)

	Thirteen weeks ended		Thirty-nine weeks ended	
	Dec. 29, 2000	Dec. 24, 1999	Dec. 29, 2000	Dec. 24, 1999
	-----	-----	-----	-----
Revenues:				
Domestic	\$ 7,241	\$ 5,535	22,664	\$15,264
International	1,609	1,220	4,101	2,661
	-----	-----	-----	-----
Cost of revenues	8,850	6,755	26,765	18,765
	3,804	2,695	10,981	7,765

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

Gross profit	5,046	4,060	15,784	10,
Operating expenses:				
Sales and marketing	3,118	1,844	8,129	5,
Research and development	598	974	2,038	2,
Web site and related costs	615	--	1,345	
General and administrative	1,229	1,004	3,787	2,
Goodwill amortization and other	196	--	504	
Total operating expenses	5,756	3,822	15,803	9,
Income (loss) from operations	(710)	238	(19)	1,
Interest and other income, net	141	223	468	
Income (loss) before taxes	(569)	461	449	1,
Provision (benefit) for income taxes	(18)	28	22	
Net income (loss)	\$ (551)	\$ 433	\$ 427	\$ 1,
Net income (loss) per share:				
Basic	\$ (0.05)	\$ 0.04	\$ 0.04	\$ 0
Diluted	\$ (0.05)	\$ 0.04	\$ 0.03	\$ 0
Shares used to compute net income (loss) per share:				
Basic	12,079	11,836	12,029	11,
Diluted	12,079	12,227	12,450	11,

See Notes to Condensed Consolidated Financial Statements

4

5

CHOLESTECH CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(IN THOUSANDS)
(UNAUDITED)

	Thirty-nine weeks ended	
	Dec. 29, 2000	Dec. 24, 1999
Cash flows from operating activities:		
Net income	\$ 427	\$ 1,699
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	2,455	1,101

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

Allowance for doubtful accounts	120	20
Changes in assets and liabilities:		
Accounts receivable	(529)	333
Inventories	(292)	1,141
Prepaid expenses and other assets	30	(176)
Other assets	--	2
Accounts payable and accrued expenses	(1,090)	591
Accrued payroll and benefits	306	582
	-----	-----
Net cash provided by operating activities	1,427	5,293
	-----	-----
Cash flows from investing activities:		
Proceeds from sale of marketable securities	4,612	22,348
Purchases of marketable securities	(5,001)	(25,301)
Purchases of property and equipment	(4,016)	(1,993)
	-----	-----
Net cash used in investing activities	(4,405)	(4,946)
	-----	-----
Cash flows from financing activities:		
Issuance of common stock	463	1,341
	-----	-----
Net cash provided by financing activities	463	1,341
	-----	-----
Net increase (decrease) in cash and cash equivalents	(2,515)	1,688
Cash and cash equivalents at beginning of period	6,959	5,529
	-----	-----
Cash and cash equivalents at end of period	\$ 4,444	\$ 7,217
	=====	=====
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	858	

See Notes to Condensed Consolidated Financial Statements

CHOLESTECH CORPORATION

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 and such principles are applied on a basis consistent with the audited financial information contained in the Annual Report on Form 10-K filed with the Securities and Exchange Commission on June 28, 2000. 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

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

conjunction with the audited consolidated financial statements contained in the Annual Report on Form 10-K for the fiscal year ended March 31, 2000. The condensed consolidated balance sheet as of March 31, 2000, has been derived from, but does not include all the disclosures contained in, the audited consolidated financial statements for the fiscal year ended March 31, 2000. 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 30, 2001.

2. BALANCE SHEET DATA

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

	Dec. 29, 2000 -----	March 31, 2000 -----
Raw materials	\$ 1,153	\$1,258
Work-in-process	1,442	1,412
Finished goods	1,411	1,044
	-----	-----
	\$ 4,006	\$3,714
	=====	=====

3. ACCOUNTING POLICIES

The Company identifies and records impairment losses on long-lived assets used in operations when events and circumstances indicate that the assets' value is less than the carrying amounts of those assets. Recoverability is measured by comparison of the assets carrying amount to future net undiscounted cash flows the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the projected discounted future net cash flows arising from the asset. None of these events

CHOLESTECH CORPORATION

have occurred with respect to the Company's long-lived assets, which consist primarily of computers and equipment, furniture and fixtures, software and leasehold improvements.

Certain financial statement items have been reclassified to conform to the current year's presentation. These reclassifications had no impact on previously reported net income (loss).

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

4. EARNINGS PER SHARE

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

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

(In thousands, except per share data)

	Thirteen Weeks Ended Dec. 29, 2000			Thirty-nine Weeks Dec. 29, 2000	
	Net Loss	Shares	Per Share	Net Income	Shares
Basic EPS	\$ (551)	12,079	\$ (0.05)	\$427	12,029
Effect of dilutive securities	--	--	--	--	421
Diluted EPS	\$ (551)	12,079	\$ (0.05)	\$427	12,450

	Thirteen Weeks Ended Dec. 24, 1999			Thirty-nine Weeks Dec. 24, 1999	
	Net Income	Shares	Per Share	Net Income	Shares
Basic EPS	\$433	11,836	\$0.04	\$1,699	11,661
Effect of dilutive securities	--	391	--	--	268
Diluted EPS	\$433	12,227	\$0.04	\$1,699	11,929

At December 29, 2000, options to purchase 870,865 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 during fiscal 2001. At December 24, 1999, options to purchase 608,731 shares of Common Stock were considered anti-

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

average fair market value of the Common stock during fiscal 2000.

5. RECENT ACCOUNTING PRONOUNCEMENTS

In November 2000, the Emerging Issues Task Force reached a consensus on Issue 00-10, "Accounting for Shipping and Handling Fees and Costs" ("EITF 00-10"). This issue provides guidance regarding how shipping and handling costs incurred by the seller and billed to a customer should be treated. EITF 00-10 concludes that all amounts billed to a customer in a sales transaction related to shipping and handling should be classified as revenue and the costs incurred by the seller for shipping and handling should be classified as cost of goods sold. Prior year financial statements have been reclassified to conform to the requirements of EITF 00-10.

In March 2000, the Emerging Issues Task Force reached a consensus on Issue 00-2, "Accounting for the Costs of Developing a Web Site" ("EITF 00-2"). In general, EITF 00-2 states that the costs of developing a web site should be accounted for under provisions of Statement of Position (SOP) 98-1, "Accounting for the Costs of Computer Software Developed or Obtained for Internal Use." The Company does not believe that it will have a material impact on its financial position, results of operations or cash flows. EITF 00-2 is effective for costs incurred after June 30, 2000.

In December 1999, the Securities and Exchange Commission ("SEC") issued Staff Accounting Bulletin No. 101 (SAB 101), "Revenue Recognition in Financial Statements. SAB 101 provides guidance for revenue recognition under certain circumstances. The accounting and disclosures prescribed by SAB 101, as amended, will be effective for the fiscal year ended March 30, 2001. The Company has implemented SAB 101 as of December 29, 2000 without a material impact on the consolidated financial statements.

During June 1998, the Financial Accounting Standards Board issued SFAS No. 133 "Accounting for Derivative Instruments and Hedging Activities" 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 in the statement of financial position and measure those instruments at fair value. The Company, to date, has not engaged in derivative and hedging activities, and accordingly, does not believe that the adoption of SFAS No. 133 will have a material impact on the financial reporting and related disclosures of the Company. The Company will adopt SFAS No. 133 as required by SFAS 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.

In March 2000, the FASB issued FIN 44, "Accounting for Certain Transactions Involving Stock Compensation - An Interpretation of APB No. 25" which is effective July 1, 2000. The adoption of FIN 44 did not have a material impact on the consolidated financial statements.

6. CONTINGENCIES

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

On February 5, 1999, a complaint entitled *Ree v. Pinckert, et al.*, No.C99-0562 (MMC) 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 Cholestech and an officer, Mr. Pinckert, violated the federal securities laws by misleading investors during the time period of July 30, 1997 - June 26, 1998, concerning the Company's business and its future prospects. On June 24, 1999, plaintiffs filed further amended complaints, which expanded the putative class period to June 28, 1996, through June 26, 1998. The amended complaint's substantive allegations and purported causes of action remain based on allegations that the Company misled shareholders concerning the Company's business and its future prospects. The complaint does not specify alleged damages. On September 20, 1999, defendants filed a motion to dismiss plaintiff's amended complaint. On March 28, 2000, the court granted defendant's motion to dismiss pursuant to rule 12(B)(6) with leave for plaintiffs to amend. The plaintiffs have filed an amended complaint. The Company intends to defend the case vigorously. The Company does not believe that the defendants in the class action 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 lawsuit will be resolved in the Company's favor. The action is in its preliminary stages and a trial date has not been set.

In September, 2000, the Company was served with a complaint, No. Ei/Ti ROCH 04002, which was filed in Vienna, Austria by Roche Diagnostics on January 13, 2000, seeking a cease and desist order barring the Company, and a distributor, from distributing HDL assay single-use test cassettes in Austria. The complaint alleges that the Company violated a Roche European patent for HDL. The Company is in the process of responding to the complaint. At this point in time no schedule has been set regarding court activity. There can be no assurance as to whether the plaintiffs will take any additional action, or whether any additional action will be resolved in the Company's favor.

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 the Company, and two distributors, from distributing HDL assay single-use test cassettes in Switzerland. The complaint alleges that the Company violated a Roche European patent for HDL. The Company has filed its 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 the Company's 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 plaintiffs will take any additional action, or whether any additional action will be resolved in the Company's favor.

In January, 2000, a complaint, No. 4 O 4/00, was filed in the District Court, Dusseldorf, Germany against the Company, and two of its distributors, seeking a cease and desist order barring the distributor from shipping HDL single-use test cassettes into Germany. The complaint alleges the Company and its distributors violated a Roche German priority patent for HDL by selling Cholestech's single-use test cassette containing a HDL assay. The Company believes the suit is without merit and intends to defend the case

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

vigorously. Therefore, the Company does 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 the Company's favor.

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

In fiscal 2000, the Company adopted Statement of Financial Accounting Standards ("SFAS") 131, "Disclosures about Segments of an Enterprise and Related Information". During fiscal 2000, the Company launched two new business units, WellCheck(TM) and WellCheck.com. As a result, the Company now has three reportable segments: Diagnostic Products, WellCheck and WellCheck.com. These segments are strategic business units that offer different products and, as a result, are managed separately. Prior to the third quarter of fiscal 2000, the Company operated in one segment, the Diagnostic Products business unit. Asset information by segment has not been presented as the Company does not produce such information. Results for the thirteen weeks ended December 29, 2000 and December 24, 1999 by segment are as follows (in thousands):

	Diagnostic Products		WellCheck		WellCheck.com	
	2000	1999	2000	1999	2000	1999
Net revenues	\$7,964	\$6,755	\$ 886	\$ --	\$ --	\$ --
Cost of revenues	3,573	2,695	231	--	--	--
Gross profit	4,391	4,060	655	--	--	--
Operating expenses:						
Sales and marketing	2,076	1,844	812	--	230	--
Research and development	598	586	--	--	--	388
Web site and related costs	--	--	--	--	615	--
General and administrative	668	593	308	--	253	411
Goodwill amortization and other	--	--	196	--	--	--
Total operating expenses	3,342	3,023	1,316	--	1,098	\$ (799)
Income (loss) from operations	\$1,049	\$1,037	\$ (661)	\$ --	\$ (1,098)	\$ (799)

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

CHOLESTECH CORPORATION

7. SEGMENT INFORMATION (CONTINUED)

Results for the thirty-nine weeks ended December 29, 2000 and December 24, 1999 by segment are as follows (in thousands):

	Diagnostic Products		WellCheck		WellCheck.com	
	2000	1999	2000	1999	2000	1999
Net revenues	\$23,611	\$18,858	\$ 3,154	\$ --	\$ --	\$ --
Cost of revenues	10,019	7,888	962	--	--	--
Gross profit	13,592	10,970	2,192	--	--	--
Operating expenses:						
Sales and marketing	5,840	5,048	1,977	--	312	--
Research and development	1,646	1,859	--	--	392	38
Web site and related Costs	--	--	--	--	1,345	--
General and administrative	1,984	1,831	814	--	989	41
Goodwill amortization and Other	--	219	504	--	--	--
Total operating expenses	9,470	8,957	3,295	--	3,038	\$ 79
Income (loss) from operations	\$ 4,122	\$ 2,013	\$ (1,103)	\$ --	\$ (3,038)	\$ (79)

11

12

CHOLESTECH CORPORATION

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

The following discussion contains forward-looking statements that involve risks and uncertainties. The Company's actual results could differ materially from those anticipated in these forward looking statements as a result of certain factors discussed below, including under "General" and "Potential Factors Affecting Future Operating Results." These forward-looking statements include, but are not limited to, the statements under "General" regarding the Company's expectation of incurring negative cash flows, the statement under "Revenues" regarding the Company's expectation that international revenues will fluctuate from period to period, the statement under "Sales and Marketing" regarding the Company's expectation that sales and marketing expenses will increase, the statement under "Research and Development" regarding the development of new test

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

cassettes and the Company's anticipation that research and development expenditures will increase, the statements under "Liquidity and Capital Resources" regarding anticipated capital spending, and internal funding for capital spending, and the statements in "Factors Affecting Future Operating Results".

GENERAL

The Company operates in three business segments:

- Diagnostic Products -- develops, manufactures and markets the Cholestech L-D-X(R) System (the "L-D-X System") which performs near-patient diagnostic testing to assist in assessing for risk of certain chronic diseases and to assist in the monitoring of therapy to treat those diseases.
- WellCheck(TM) -- conducts convenient consumer testing within the United States to assess for risk of certain chronic diseases and to assist in the monitoring of therapy to treat those diseases. Combined with the WellCheck.com web site, consumers are able to build their own personal health management program.
- WellCheck.com -- provides through Test Event Activity Management System ("TEAMS") software patient data capture and summary reporting to sponsors. Additionally through the Internet, interactive tools enabling individuals to partner with a team of virtual experts to help them manage their own risk of certain chronic diseases and to monitor and motivate personal health management of those diseases.

Diagnostic Products currently markets the L-D-X(R) System, including the L-D-X Analyzer and a variety of single use test cassettes, to the physician office laboratory market, and the health promotion market in the United States and Internationally. The L-D-X System is capable of measuring multiple analytes simultaneously with a single drop of whole blood, producing test results within five minutes. The Company's current products measure and monitor blood cholesterol, related lipids, glucose, and liver function, and are used to perform testing of patients at risk of, or suffering from cardiovascular disease, diabetes or liver disease.

CHOLESTECH CORPORATION

WellCheck currently provides consumer-testing services utilizing the Cholestech L-D-X(R) System, as well as various other technologies for the assessment of cholesterol, blood pressure, osteoporosis, glycated hemoglobin and general health assessment. WellCheck was initiated through the acquisition of Health Net, Inc. in January of 2000, for approximately \$3.7 million, including closing costs. The Company intends to expand the WellCheck testing services offered through a combination of further acquisitions or partnerships and internal development with the goal of creating the first truly nationwide consumer testing service for chronic disease. Substantially all of the revenue of the WellCheck business is currently derived from promotional programs with major pharmaceutical companies marketing lipid-lowering statin drugs. The Company believes that there is an opportunity to further expand the WellCheck business into retail testing venues and worksite wellness programs. As WellCheck expands consumer testing, demand for single use cassettes, provided by the Diagnostic Products business unit, will also increase.

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

WellCheck.com consists of the web site content and structure, TEAMS software, and business unit infrastructure, and was launched in June, 2000. In collaboration with their healthcare providers, consumers will have at their disposal tools needed to learn about and manage certain chronic diseases.

The Company may incur negative cash flows from operations in the Diagnostic Products business unit as it expands manufacturing capacity for existing and new test cassettes, increases product research and development efforts for new test cassettes, expands sales and marketing activities, and pursues regulatory clearances and approvals. The development and commercialization of new tests will require additional development, sales and marketing, manufacturing and other expenditures. The required level and timing of such expenditures will have an impact on the Company's ability to maintain profitability and positive cash flows from operations.

The continued development and maintenance of WellCheck.com, as well as the acquisition and other startup costs relating to WellCheck, may also result in negative cash flows for the Company. 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 the Company's ability to maintain profitability and positive cash flows from the new business units.

The Company expects its revenue mix of the three segments to change from time to time and these changes will affect the Company's overall revenues and operating results.

Within the Diagnostic Products business, the Company generally has found that customers in the POL market use a higher proportion of lipid profile cassettes for therapeutic monitoring purposes. These test cassettes typically have higher selling prices and associated gross margins than the Company's other tests. However, the Company has also experienced a relatively lower rate of testing per day in this market than in the health promotion market, which focuses mainly on risk assessment and experiences a higher rate of testing with a lower proportion of lipid profile cassettes.

13

14

CHOLESTECH CORPORATION

WellCheck's revenue will change 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 revenues will be influenced by seasonality. During the last two months of the calendar year, people are pursuing other interests, and are less focused on chronic health issues. Additionally, during the summer months consumers' attention is also less focused on chronic health issues.

WellCheck.com's revenues are based on TEAMS software and the Internet, which is new to the Company, and remains uncertain. Revenue will be generated by the use of TEAMS software, and sponsorship on the web site. Revenue will depend on the number of persons visiting the site and the perceived value to sponsors and advertisers. To date the Company has not signed a revenue generating agreement with a sponsor or advertiser related specifically to WellCheck.com.

The Company is currently in feasibility studies for additional tests for diagnostic screening and high cholesterol. These new tests are in various stages of feasibility, and the Company will be required to undertake time consuming and costly development activities and seek regulatory approval for these new tests

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

before such tests can be marketed. The Company believes that revenue growth, if any, and future operating results will depend, in part, upon completing development of and successfully introducing these tests. The Company received 510(k) clearance to market the Alanine Aminotransferase (ALT) test for liver function in September, 1999. Subsequently, in September, 1999, the Company submitted the ALT test to the Center for Disease Controls and Prevention ("CDC") seeking Clinical Laboratory Improvement Amendments of 1988, as amended, ("CLIA") waived status. In January, 2000, responsibility for CLIA waiver was transferred to the Food and Drug Administration ("FDA"). The Company cannot estimate when the FDA will determine whether to grant CLIA waived status for this test or whether such waived status will be granted.

RESULT OF OPERATIONS

THIRTEEN WEEKS ENDED DECEMBER 29, 2000, AND DECEMBER 24, 1999
AND
THIRTY-NINE WEEKS ENDED DECEMBER 29, 2000, AND DECEMBER 24, 1999

Revenues. During the thirteen weeks ended December 29, 2000, revenues increased 31% to \$8.9 million from \$6.8 million in the thirteen weeks ended December 24, 1999. Diagnostic Products represented 90% and 100% of our revenues for the third quarter of fiscal 2001 and 2000, respectively. During the thirteen weeks ended December 29, 2000, WellCheck represented 10% of our revenues.

International revenues increased by 32% or \$389,000 from \$1.2 million to \$1.6 million for the thirteen weeks ended December 29, 2000, compared to the same period in fiscal 2000. The Diagnostic Products segment generated all international revenue.

14

15

CHOLESTECH CORPORATION

During the first thirty-nine weeks of fiscal 2001, revenues increased 42% to \$26.8 million from \$18.9 million in the first thirty-nine weeks of fiscal 2000. Diagnostic Products represented 88% and 100% of our revenues for the thirty-nine weeks ended December 29, 2000 and December 24, 1999, respectively. WellCheck contributed 12% of the revenues for the thirty-nine weeks ended December 29, 2000.

International revenues increased by 42% or \$1.2 million from \$2.9 million to \$4.1 million for the thirty-nine weeks ended December 24, 1999 and December 29, 2000, respectively. All international revenues were generated by Diagnostic Products segment.

Segment performance was as follows:

- Diagnostic Products revenue increased \$1.2 million, or 18%, from \$6.8 million in the thirteen weeks ended December 24, 1999 to \$8.0 million in the thirteen weeks ended December 29, 2000. The largest increase related to a \$933,000 or 17% improvement in sales of single use test cassettes, which increased in the POL and international markets. Additionally, sales of L-D-X Analyzers were \$360,000 or 47% higher.

For the thirty-nine weeks ended December 29, 2000, revenue increased \$4.7 million or 25%, to \$23.6 million, from \$18.9 million for the

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

thirty-nine weeks ended December 24, 1999. Single use test cassettes sales volume increased by \$3.7 million or 24%, primarily in the POL and International market segments, accounting for most of the revenue increase. L-D-X Analyzer sales increased by \$1.1 million or 56% representing unit growth in all market segments other than pharmacy.

- WellCheck revenue totaled \$886,000 in the thirteen weeks ended December 29, 2000. For the thirty-nine weeks ended December 29, 2000 total revenue was \$3.2 million. This business unit was not operating during the thirty-nine weeks ended December 24, 1999.
- As of December 29, 2000, WellCheck.com had not generated revenue.

Cost of Revenues. Cost of revenues increased 41% to \$3.8 million for the thirteen weeks ended December 29, 2000, from \$2.7 million for the thirteen weeks ending December 24, 1999. Gross margins were 57% and 60% for the thirteen weeks ended December 29, 2000, and December 24, 1999, respectively. Diagnostic Products accounted for 94% and WellCheck accounted for 6% of the cost of revenues for the thirteen weeks ending December 29, 2000. For the thirteen weeks ending December 24, 1999 Diagnostic Products accounted for 100% of the cost of revenues.

For the thirty-nine weeks ending December 29, 2000, the cost of revenues increased \$3.1 million, or 39%, to \$11.0 million, from \$7.9 million for the thirty-nine weeks ending December 24, 1999. Gross margins were 59% and 58% for the thirty-nine weeks ending December 29, 2000 and December 24, 1999, respectively. Diagnostic Products accounted for 91% of the cost of revenues for the thirty-nine weeks ending December 29, 2000 and 100% for the thirty-nine weeks ending December 24, 1999. WellCheck accounted for 9% of the cost of revenues for the thirty-nine weeks ending December 29, 2000.

15

16

CHOLESTECH CORPORATION

Segment performance was as follows:

- Diagnostic Products cost of revenues includes direct labor, direct material, overhead and royalties. Cost of revenues increased 33%, on an 18% increase in sales, to \$3.6 million in the thirteen weeks ended December 29, 2000, from \$2.7 million in the thirteen weeks ended December 24, 1999. Gross margin declined to 55% of total revenues in the thirteen weeks ended December 29, 2000, from 60% of revenues in the thirteen weeks and December 24, 1999. The decrease in gross margin was the result of a higher indirect labor staffing and more material consumption, including scrap in the production of single use test cassettes without a corresponding increase in production volume. The validation of the new production line generated additional non-recurring costs.

The cost of revenues increased by \$2.1 million, or 27%, to \$10.0 million from \$7.9 million for the thirty-nine weeks ending December 29, 2000 and December 24, 1999, respectively. Gross margin remained constant at 58% for the thirty-nine weeks ending December 29, 2000 and the thirty-nine weeks ending December 24, 1999.

- WellCheck cost of revenues includes travel expenses, laboratory services, medical waste disposal, and the cost of medical testing

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

equipment and supplies. Costs of product provided by the Company's Diagnostic Products business are eliminated upon consolidation. For the thirteen weeks ending December 29, 2000, total cost of revenues was \$231,000 or 26% of revenue. For the thirty-nine weeks ending December 29, 2000 cost of revenues was \$962,000, or 30% of revenue, resulting in a gross margin of 70%.

- WellCheck.com did not generate cost of revenues.

Sales and Marketing Expense. Sales and marketing expense includes salaries, commissions, bonuses, expenses for outside services related to marketing programs, and travel. Additionally, WellCheck sales and marketing expense includes salaries and related costs of the health promotion associates who perform consumer testing. Sales and marketing expense increased 69%, or \$1.3 million, to \$3.1 million in the thirteen weeks ended December 29, 2000, from \$1.8 million in the thirteen weeks ended December 24, 1999. Sales and marketing expense increased to 35% of revenue in the third quarter of fiscal 2001 from 27% in the third quarter of fiscal 2000 due mainly to the addition of WellCheck and WellCheck.com. Diagnostic Products accounted for 67%, WellCheck accounted for 26%, and WellCheck.com accounted for 7% of sales and marketing expense for the thirteen weeks ending December 29, 2000

For the first thirty-nine weeks of fiscal 2001, sales and marketing expense was \$8.1 million compared to \$5.0 million for the first thirty-nine weeks ending December 24, 1999. As a percent of revenue, sales and marketing expense increased to 30% from 27% for the thirty-nine weeks ending December 29, 2000 and December 24, 1999, respectively also due to the addition of WellCheck and WellCheck.com. Diagnostic Products was 72% of sales and marketing expense for the first thirty-nine weeks ending December 29, 2000; WellCheck was 24% and WellCheck.com was 4%.

Sales and marketing expense in each of Cholestech's segments was as follows:

- Diagnostic Products sales and marketing expense increased 13% to \$2.1 million in the thirteen weeks ending December 29, 2000, from \$1.8 million for the thirteen weeks

16

17

CHOLESTECH CORPORATION

ending December 24, 1999. The increase can be attributed to increased commissions, public relations, advertising, distributor relations and other marketing activities. Sales and marketing expense decreased to 26% of revenue for the thirteen weeks ending December 29, 2000, from 27% in the corresponding period for fiscal 2000.

For the thirty-nine weeks ending December 29, 2000, Diagnostic Products sales and marketing expense increased by \$792,000 to \$5.8 million from \$5.0 million for the thirty-nine weeks ending December 24, 1999. Most of the increase was attributed to increased staffing resulting in higher wage and related costs. Additionally advertising, public relations, and other promotional expenses increased.

- WellCheck sales and marketing expense was \$812,000 for the thirteen weeks ending December 29, 2000. WellCheck did not operate during the thirteen weeks ending December 24, 1999. WellCheck sales and marketing expense was 92% of WellCheck revenues for the third quarter of fiscal 2001. A large portion of the expense, for the quarter was to complete a

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

demonstration retail-testing program. The demonstration program was not intended to be profitable, but sponsorship did cover 19% of the total project cost. Sales and marketing expense contained 74% of the project cost. For the thirty-nine weeks ending December 29, 2000 sales and marketing expense was \$2.0 million or 63% of revenue.

- WellCheck.com sales and marketing expense was \$230,000 for the thirteen weeks ending December 29, 2000. For the thirty-nine weeks ending December 29, 2000 sales and marketing expense was \$312,000. WellCheck.com did not operate during the thirty-nine weeks ending December 24, 1999.

Research and Development Expenses. Research and development expense includes salaries, bonuses, outside services, supplies, and depreciation of capital equipment. Research and development expense decreased 39% to \$598,000 in the thirteen weeks ended December 29, 2000, from \$974,000 in the thirteen weeks ended December 24, 1999. Research and development expenses as a percentage of revenues decreased to 7% for the thirteen weeks ended December 29, 2000, from 15% for the thirteen weeks ended December 24, 1999. The Diagnostic Products business unit represented 100% and 60% of the Company's research and development expenses for the thirteen weeks ended December 29, 2000, and December 24, 1999, respectively. WellCheck.com accounted for 40% of the research and development expense during the thirteen weeks ending December 24, 1999.

During the first thirty-nine weeks of fiscal 2001, research and development expense was \$2.0 million, down 9% from \$2.2 million for the corresponding period of fiscal 2000. Diagnostic products accounted for 81%, and WellCheck.com accounted for 19% of the total expense for the thirty-nine weeks ending December 29, 2000. During the thirty-nine weeks of fiscal 2000, Diagnostic products incurred 83% of the expense and WellCheck.com incurred 17% expense. Research and development cost declined as percentage of revenue to 8% during for the first thirty-nine weeks ending December 29, 2000, from 12% for the thirty-nine weeks ending December 24, 1999.

Research and development expense in each of Cholestech's segments was as follows:

17

18

CHOLESTECH CORPORATION

- For the thirteen weeks ending December 29, 2000, Diagnostic Products research and development expense increased by \$12,000, or 2%, to \$598,000 compared to \$586,000 in the corresponding period ending December 24, 1999.

During the thirty-nine weeks ended December 29, 2000, research and development expense decreased by \$213,000, or 11%, to \$1.6 million from \$1.9 million for the thirty-nine weeks ending December 24, 1999. Reduced spending is due to the lower level of development activity incurred since the ALT single test cassettes were submitted to the FDA for a CLIA waiver.

- WellCheck incurred no research and development expense costs in either the thirteen weeks ending December 29, 2000 or thirty-nine weeks ending December 29, 2000.
- WellCheck.com incurred no research and development expense during the

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

thirteen weeks ending December 29, 2000.

During the thirty-nine weeks ending December 29, 2000, research and development expense of \$392,000 was incurred compared to \$388,000 for the thirty-nine weeks ending December 24, 1999. This represents certain period costs of web site development incurred prior to the launch of the web site. Since the launch of our web site at the beginning of July, all operating costs have been captured under the heading "Web Site and Other Related Costs".

Web Site and Related Costs. Web site and related costs include web site amortization, compensation and benefits, web hosting, site maintenance, content and other outside services relating to the operations of the WellCheck.com web site and TEAMS software. For the thirteen weeks ending December 29, 2000, expense was \$615,000 or 7% of revenue. All costs were incurred by WellCheck.com, which did not have any revenue during the quarter.

For the thirty-nine weeks ending December 29, 2000, during which the web site operated for twenty-six weeks, expense was \$1.3 million or 5% of revenue. The WellCheck.com segment incurred all expenses.

General and Administrative Expense. General and administrative expense includes compensation, benefits, and expenses for outside professional services including information services, legal, and accounting. General and administrative expense increased 23% to \$1.2 million in the thirteen weeks ended December 29, 2000, from \$1.0 million in the thirteen weeks ended December 24, 1999. General and administrative expense decreased to 14% of revenues in the thirteen weeks ended December 29, 2000, from 15% in the thirteen weeks ended December 24, 1999. The Diagnostic Products business unit represented 54%, WellCheck 25%, and WellCheck.com 21% of the Company's general and administrative expenses for the thirteen weeks ended December 29, 2000. Diagnostic Products accounted for 59%, and WellCheck.com accounted for 41% of the general and administrative expenses for the third quarter of fiscal 2000.

For the thirty-nine weeks ending December 29, 2000, general and administrative expense increased \$1.6 million, or 69% from \$2.2 million to \$3.8 million for the thirty-nine weeks ending December 24, 1999. General and administrative expense increased to 14% of revenue for the thirty-nine weeks ending December 29, 2000 from 12% for the thirty-nine weeks ending December 24, 1999. The Diagnostic Products business unit represented 52% of expense, WellCheck.com represented 26% and WellCheck represented 22% in the thirty-nine weeks

18

19

CHOLESTECH CORPORATION

ending December 29, 2000. During the first thirty-nine weeks of fiscal 1999, Diagnostic Products represented 82%, and WellCheck.com represented 18% of the total expense.

General and administrative expense in each of Cholestech's segments was as follows:

- Diagnostic Products general and administrative expense increased by 13% to \$668,000 for the thirteen weeks ended December 29, 2000 from \$593,000 in the thirteen weeks ending December 24, 1999. The increase was the impact of additional headcount, which resulted in increased wages and

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

other related costs.

For the thirty-nine weeks ending December 29, 2000 expenses increased by 8% to \$2.0 million from \$1.8 million for the first thirty-nine weeks of fiscal 2000. The increase was attributed to the infrastructure needed for the business unit. During the prior fiscal year, Diagnostic Products did not have dedicated administration until the third quarter of fiscal 2000. This increase in cost was partially offset by the allocation of shared expenses to the new business units.

- WellCheck general and administrative expense was \$308,000 during the thirteen weeks ending December 29, 2000 and \$814,000 for the thirty-nine weeks ending December 29, 2000. No related expenses were incurred during the thirty-nine weeks ending December 24, 1999. The expense for the new business unit did not start until the fourth quarter of fiscal 2000.

- WellCheck.com general and administrative expense decreased by 38% to \$253,000 for the thirteen weeks ending December 29, 2000 from \$411,000 for the thirteen weeks ending December 29, 1999. The decrease was mainly attributed to a \$105,000 decline in shared expenses and a \$59,000 transfer of the division Chief operating officer expense to WellCheck.

For the thirty-nine weeks ending December 29, 2000, expense increased by 141% to \$989,000 from \$411,000 for the thirty-nine weeks ending December 24, 1999. This was attributed to WellCheck.com only operating for thirteen weeks during the thirty-nine weeks ending December 24, 1999.

Goodwill amortization and other. The expense for the thirteen weeks ending December 29, 2000 was \$196,000 with no comparable expense for the thirteen weeks ending December 24, 1999. The fiscal 2001 expenses relate exclusively to the amortization of goodwill incurred upon the acquisition of Health Net, Inc. in January, 2000

For the thirty-nine weeks ending December 29, 2000, expense increased 130% to \$504,000 from \$219,000 in the thirty-nine weeks ending December 24, 1999. All the charges for the current fiscal year relate to the amortization of Health Net goodwill, which did not start during the thirty-nine weeks ending December 24, 1999. The expense for the thirty-nine weeks ending December 24, 1999 included \$98,000 charges related to the Company's defense of a putative class action lawsuit.

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 37% to

CHOLESTECH CORPORATION

\$141,000 in the thirteen weeks ended December 29, 2000 from \$223,000 in the thirteen weeks ended December 24, 1999. The decrease was the result of lower investment balances in marketable securities

Income Taxes. As the Company has significant tax credit carry forwards, the provision for income taxes for the thirty-nine weeks ended December 29, 2000 primarily represents the estimated alternative minimum tax. Management expects

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

to utilize additional net operating loss and other tax carry forward amounts to the extent income is earned during fiscal 2001. The Company's estimated effective tax rate is expected to remain below the federal statutory rate throughout fiscal 2001.

LIQUIDITY AND CAPITAL RESOURCES

The Company has financed its operations primarily through the sale of equity securities and from positive cash flows from operations. From inception to December 29, 2000, the Company raised \$72.7 million in net proceeds from equity financing. As of December 29, 2000, the Company had \$12.7 million of cash, restricted cash, cash equivalents and marketable securities. Restricted cash was \$1.0 million, which is being held in escrow, for the final resolution of the Health Net purchase. In addition to these amounts, the Company has available an \$8.0 million revolving bank line of credit. While the line of credit is in effect, the Company is 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 December 29, 2000, there were no borrowings outstanding under the line of credit.

During the first thirty-nine weeks of fiscal 2001, the Company provided \$1.4 million of cash from operating activities compared to net cash provided of \$5.3 million in the first thirty-nine weeks of fiscal 2000. The net cash provided from operations in the first thirty-nine weeks of fiscal 2001 was comprised of net income of \$427,000 and adjustments for non-cash items including \$2.5 million for depreciation and amortization. This was partially offset by a combined \$821,000 increase in accounts receivable and inventory. Also, accounts payable and accrued expenses decreased by \$1.1 million, further consuming cash. In the corresponding thirty-nine weeks of fiscal 2000, net cash was provided by net income of \$1.7 million plus adjustments for non-cash items, mainly \$1.1 million of depreciation. Additionally, working capital, excluding cash, equivalents, and marketable securities decreased by \$2.5 million.

Net cash used in investing activities was \$4.4 million in the first thirty-nine weeks of fiscal 2001, consisting primarily of additional capitalized web site development costs of \$1.2 million, the purchase of \$2.1 million of equipment and lease hold improvements and \$318,000 for additional Health Net purchase price. Additionally, there was a net purchase of \$389,000 in marketable securities. For the first thirty-nine weeks of fiscal 2000, the Company purchased \$2.0 million of capital equipment.

Proceeds from the Company's associate stock option exercises and associate stock purchase programs provided \$463,000 in the first thirty-nine weeks of fiscal 2001. For the corresponding

thirty-nine weeks of fiscal 2000, \$1.3 million was provided by exercises of options pursuant to the Company's associate stock incentive and associate stock purchase programs.

During the fourth quarter of fiscal 2001, the Company intends to expend approximately \$1.6 million, including \$1.0 million of restricted cash, for capital purchases related to web site or TEAMs software, expansion of its WellCheck testing service, expansion of its manufacturing capacity, and research and development. As of December 29, 2000, however, contracts have not been

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

signed and schedules have not been set. Accordingly, non-cancelable purchase commitments at December 29, 2000 were not material.

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

The Company's 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 the Company seeks to develop; the successes of these development efforts; the costs and timing of expansion of sales and marketing activities; the extent to which the Company's existing and new products gain market acceptance; competing technological and market developments; the progress of commercialization efforts of the Company's 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 and CLIA; and other factors.

In the event that additional financing is needed, the Company may seek to raise additional funds through debt, public or private financing, collaborative relationships or arrangements. However, the Company may not be successful in obtaining necessary funds. Even if the Company does raise funds, any additional equity financing may be dilutive to shareholders, and debt financing may involve restrictive covenants that limit the manner in which the Company may be operated. Collaborative arrangements, if necessary to raise additional funds, may require the Company to relinquish its rights to certain of its technologies, products or marketing territories. The failure of the Company to raise capital on acceptable terms when needed could have a material adverse effect on the Company's business, financial condition and results of operations. See "--Potential Factors Affecting Future Operating Results--Possible Future Capital Requirements: Uncertainty of Additional Funding".

NEW ACCOUNTING PRONOUNCEMENTS

In November 2000, the Emerging Issues Task Force reached a consensus on Issue 00-10, "Accounting for Shipping and Handling Fees and Costs" ("EITF 00-10"). This issue provides guidance regarding how shipping and handling costs incurred by the seller and billed to a customer should be treated. EITF 00-10 concludes that all amounts billed to a customer in a

CHOLESTECH CORPORATION

sales transaction related to shipping and handling should be classified as revenue and the costs incurred by the seller for shipping and handling should be classified as cost of goods sold. Prior year financial statements have been reclassified to conform to the requirements of EITF 00-10.

In March 2000, the Emerging Issues Task Force reached a consensus on Issue 00-2, "Accounting for the Costs of Developing a Web Site" ("EITF 00-2"). In general, EITF 00-2 states that the costs of developing a web site should be accounted for under provisions of Statement of Position (SOP) 98-1, "Accounting for the Costs of Computer Software Developed or Obtained for Internal Use." The

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

Company does not believe that it will have a material impact on its financial position, results of operations or cash flows. EITF 00-2 is effective for costs incurred after June 30, 2000.

In December 1999, the Securities and Exchange Commission ("SEC") issued Staff Accounting Bulletin No. 101 (SAB 101), "Revenue Recognition in Financial Statements. SAB 101 provides guidance for revenue recognition under certain circumstances. The accounting and disclosures prescribed by SAB 101, as amended, will be effective for the fiscal year ended March 30, 2001. The Company has implemented SAB 101 as of December 29, 2000 without a material impact on the consolidated financial statements.

During June 1998, the Financial Accounting Standards Board issued SFAS No. 133 "Accounting for Derivative Instruments and Hedging Activities" 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 in the statement of financial position and measure those instruments at fair value. The Company, to date, has not engaged in derivative and hedging activities, and accordingly, does not believe that the adoption of SFAS No. 133 will have a material impact on the financial reporting and related disclosures of the Company. The Company will adopt SFAS No. 133 as required by SFAS 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.

In March 2000, the FASB issued FIN 44, "Accounting for Certain Transactions Involving Stock Compensation - An Interpretation of APB No. 25" which is effective July 1, 2000. The adoption of FIN 44 did not have a material impact on the consolidated financial statements.

POTENTIAL FACTORS AFFECTING FUTURE OPERATING RESULTS

Cholestech has no prior experience in the testing services or Internet health management businesses, and if these new businesses are not successful, Cholestech will be greatly harmed. The testing services business and Internet health management business to be pursued by Cholestech's WellCheck and WellCheck.com business units are completely new to Cholestech and our management team. This will make it more difficult for us to successfully develop these new businesses. Also, we will be devoting significant resources to developing these new businesses. If we are not successful in developing these new businesses, our Diagnostics business will be greatly harmed. Even if we are successful at developing the new businesses, the demands of attempting to grow these new businesses may prevent us from devoting significant time and attention to our traditional business, and that traditional business may decline.

CHOLESTECH CORPORATION

Internet health management is a new and unproven business, which means that there is more risk that this business will not succeed, resulting in financial harm to Cholestech. The internet-based personal health management business is a very new and as yet unproven business. If it does not succeed, our significant investment in this business will result in significant financial harm to Cholestech. Cholestech's success in this business will depend upon individual acceptance of internet-based management of personal health information. Consumers may not feel comfortable having their health-related information available over the Internet despite the privacy and security measures we plan to

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

take. Or there may be other reasons that we have not thought of that could result in Internet health management not being a viable business. Thus, consumers may not use our health management system on the Internet, and our significant investment in this new business would not be recovered. This would result in a significant financial loss to Cholestech.

We have no significant experience in managing geographically diverse operations. If we are not successful in this area, our geographically dispersed testing business may not perform well, which would result in financial harm to Cholestech. Our traditional business has been managed and operated almost exclusively from our Hayward, California headquarters. The new WellCheck business will require us to operate in multiple geographic locations. This will require us to manage multiple, geographically dispersed businesses and adapt our management and financial systems and controls to this new geographically dispersed business. We may not be able to manage these changes rapidly, successfully, or at all. If we cannot successfully manage our geographic expansion, the testing business will be much less likely to succeed. This would mean we are less likely to recover our large investment in the testing business. This, in turn, would likely result in significant financial harm to Cholestech.

Our new testing and Internet health management businesses will require significant financial resources to develop. These expenditures will hurt our overall short term financial performance and, if these new businesses are not successful, this large financial investment will not be returned. This will result in significant financial damage to Cholestech. The development of the two new business units, and the WellCheck.com Internet business in particular, will require significant start-up expenditures. These expenditures are likely to materially affect the operating results of Cholestech as a whole. The Company 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 Cholestech. Also, equity issued by us may have rights, preferences, or privileges senior to those of our existing shareholders. We plan to use acquisitions 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. The WellCheck business will be developed in significant part by our acquiring existing testing service businesses. We may acquire services and/or technology to assist in developing our WellCheck.com business as well. Any acquisition could result in significant amounts of cash, potentially dilutive issuances of equity securities, and/or the incurring of debt or amortization

CHOLESTECH CORPORATION

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. These difficulties could also result in diversion of management attention, which could prevent the new businesses from being successful. Any of these results

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

could harm Cholestech financially.

Our new Internet health management business has information security risks that could result in the business not succeeding or in financial liability for Cholestech. Our planned WellCheck.com business will involve the provision and management of individual health-related information over the Internet. Despite security measures we plan to take, such information may be accessed or manipulated by third parties without our consent or the consent of the user of our service. Any such security breach could greatly erode consumer confidence in our WellCheck.com business. This would likely severely harm that business and its prospects. Additionally, if an individual's health information is corrupted by software or technical problems, consumer confidence in the WellCheck.com business could be severely damaged. If consumer information is altered by third parties or by technical problems, the affected individual may bring litigation against Cholestech and/or the Company's web site hosting partners. Any such litigation could result in significant expense, including any damage awards. Even if ultimately decided in our favor, such litigation could result in significant expense and distraction of our management.

Our L-D-X System has not yet achieved broad market acceptance in all of our target markets and in physician office laboratories and pharmacies, market acceptance has proceeded slower than anticipated. If broad market acceptance does not occur, Cholestech will not grow and will suffer significant financial damage. The Cholestech L-D-X(R) 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 Company's Diagnostic Products revenues for the foreseeable future. If this revenue does not grow, the overall business will be severely harmed. In order for the Company to increase revenues, sustain profitability and maintain positive cash flows from operations, the L-D-X System must gain much broader market acceptance among health care providers, particularly physician office laboratories and pharmacies. Cholestech has made only limited sales to physician office laboratories and pharmacists to date. Market acceptance issues such as awareness, adoption, reimbursement, distribution, pricing, and education have kept sales to pharmacists at a significantly low level to date relative to the size of the available market. If we do not achieve broad market acceptance, Cholestech's Diagnostic Products business will not grow. This will result in significant financial damage to the business as a whole. We are relying in significant part on income from the core Diagnostic Product business to finance the Company's strategic expansion. If the Diagnostic Products business does not grow, the new businesses will not succeed. These results will cause severe financial harm to Cholestech. Factors that could prevent broad market acceptance of the L-D-X System include:

- Awareness of the availability of the Company's technology remains at predominantly low levels in both the physician and pharmacy customer groups.

24

25

CHOLESTECH CORPORATION

- The L-D-X System must be an attractive alternative to other means of testing. This determination will depend on the L-D-X System's accuracy, ease of use, rapid test time, reliability and cost effectiveness compared to other testing alternatives.
- Even if the advantages of the L-D-X System in diagnosing and monitoring patients with chronic diseases are established, health care providers may elect not to purchase and use the L-D-X System for any number of reasons. For example, physicians and other health care providers may not change their established means of having such tests performed or may not

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

make the necessary investment to purchase the L-D-X Analyzer.

- The growing prevalence of managed care may adversely affect the physician office laboratory market. A growing number of physicians are salaried employees and have no financial incentive to perform testing.
- 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.
- Market acceptance of the L-D-X System will in part depend on the continued availability and amount of reimbursement for performing tests on the L-D-X System.
- Even if the Company is successful in continuing to place L-D-X Analyzers at POLs, pharmacies and other near-patient testing sites, there can be no assurance that placement of L-D-X Analyzers will result in sustained demand for the Company's single use test cassettes.

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 revenues and profits from operations. Because the L-D-X System currently contributes the vast majority of our revenues, Cholestech 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. Results are likely to continue to fluctuate and we may (especially in light of investment in our new businesses) experience losses in the future. Historically, Cholestech has experienced significant operating losses and negative cash flows from operations. As of December 29, 2000, we had an accumulated deficit of \$45.0 million. Cholestech's first profitable quarter was the second quarter of fiscal 1998, and our first profitable year was fiscal 1998. However, we recorded a net loss of \$73,000 for fiscal 1999, before returning to profitability in fiscal 2000. Cholestech's profitability and positive cash flows from operations in the future will require:

- Broadening market acceptance of our existing diagnostic product offerings.
- Completing the development, successful introduction and marketing of additional cassette based tests or other products for the Diagnostic Products business unit.

25

26

CHOLESTECH CORPORATION

- Successfully developing our new testing services and Internet health management businesses.

Cholestech may experience significant fluctuations in revenues and results of operations on a quarter to quarter basis in the future. Quarterly operating results will fluctuate due to numerous factors, including:

- The timing and amount of expenditures required for the continued development of our new testing services and Internet health management businesses.

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

- 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.
- Our ability to reduce the cost of cassette manufacturing.
- 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 the Company's 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.
- Variations in the mix of products sold.
- General economic conditions.

These and other factors are difficult to predict, and could have a material adverse effect on Cholestech's 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 upon 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 revenues. This also means that Cholestech's results will likely not meet the expectations of public market security analysts or investors at one time or another. This could cause the trading price of Cholestech's common stock to decline significantly.

In order to grow the Diagnostic Products business significantly, Cholestech must successfully develop, introduce and market new tests. These activities are very costly and, if not successful, could result in significant financial harm to Cholestech's business. The vast majority of Cholestech's revenues come from its Diagnostics Products business. We anticipate this will continue for the near term. Cholestech is also relying on revenue from the Diagnostics Products

business to fund the development of its new testing services and Internet health management businesses. Cholestech also believes that its Diagnostic Products business will not grow significantly if it does not develop new tests to use with the L-D-X System. If new tests are not developed and accepted in the

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

market, Cholestech's business will not grow significantly and the business 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 prior to 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.
- A new test must be able to be manufactured in a reliable, cost-efficient, high-volume manufacturing process for such tests and the manufacturing process must be developed and implemented in a timely manner in order to produce the test for sale.
- New tests must meet a significant market need in order to be successful.
- New tests must obtain proper regulatory approvals to be marketed.

Cholestech could experience difficulties that could delay or prevent the successful development, introduction and marketing of new tests. Also, regulatory clearance or approval of any new tests may not be granted on a timely basis, or at all.

Cholestech has experienced difficulties obtaining regulatory approval for tests in the past. In September 1999, the FDA approved the Company's request for clearance to market Cholestech's newly developed ALT single use test cassette. As of June 2000, the FDA has not approved our request for CLIA waiver for the use of the ALT test cassette with the L-D-X System. Because the FDA's evaluation of applications for CLIA waived status is not based upon precisely defined, objectively measurable criteria, Cholestech cannot predict the likelihood of obtaining waived status in the future for the ALT product or other products. In order to successfully commercialize the ALT test cassette or other future tests in the United States, the Company believes it is critical to obtain waived status under CLIA. In order to successfully commercialize any new tests, including the ALT test cassette, the Company will be required to establish and maintain reliable, cost-efficient, high-volume manufacturing capacity for such tests.

Cholestech has in the past encountered difficulties in scaling up production of new test cassettes, including problems involving production yields, quality control and assurance, variations and impurities in raw materials and performance of the manufacturing equipment.

Manufacturing Cholestech's tests cassettes is a complex and delicate process and interruption of cassette manufacturing could result in insufficient cassettes to meet orders, which could result in financial harm to Cholestech. Cholestech internally manufactures 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. The Company has, in the past, experienced lower than expected manufacturing yields that have adversely affected gross margins and delayed product shipments. To the extent that the Company does not maintain acceptable manufacturing yields of test cassettes or experiences product

CHOLESTECH CORPORATION

shipment delays, the Company's business, financial condition and results of operations would be materially adversely affected. Manufacturing yields could be harmed by:

- Raw materials variations or impurities,
- Occurrence of manufacturing process variances,
- Decreased manufacturing equipment performance, and
- Introduction of manufacturing environment impurities.

Cholestech's cassette manufacturing lines would be costly and time consuming to repair or replace if the operation were interrupted. The interruption of cassette manufacturing operations or the loss of employees dedicated to the cassette manufacturing facility could severely harm Cholestech's business. The risks involving the manufacturing lines include:

- As Cholestech's production levels have increased, Cholestech has been required to use its machinery more hours per day and the down time resulting from equipment failure has increased.
- The custom nature of much of Cholestech's manufacturing equipment increases the time required to remedy equipment failures and replace equipment.
- Cholestech has a limited number of employees dedicated to the operation and maintenance of the cassette manufacturing equipment, the loss of whom could impact Cholestech's ability to effectively operate and service such equipment.
- Cholestech manufactures all cassettes at its 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, that is, 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 no alternate sources of power in the event of a blackout, and 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.

Cholestech will need to reduce manufacturing costs in order to achieve long-term success, and it may not be able to reduce these costs. We believe that

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

we will be required to reduce manufacturing costs for new and existing test cassettes in order to achieve sustained profitability. Cholestech currently operates two manufacturing lines for dry chemistry cassettes. We are installing and validating a third manufacturing line that we anticipate will become fully operational in the fourth quarter of fiscal 2001. The complexity and custom nature of our manufacturing process increases the amount of time and money required to add an additional

28

29

CHOLESTECH CORPORATION

manufacturing line. Despite our efforts, the new cassette manufacturing line may not be completed in a timely fashion, or at all. 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.

Cholestech may have to develop new manufacturing processes and a new manufacturing line in order to market immunoassay tests in development, or we will not be able to recover the costs of these tests in development. We may also be required to build a new cassette manufacturing line in order to manufacture the immunoassay test cassettes under development. To date, we have not developed the processes and production equipment necessary for an immunoassay cassette manufacturing line. Failure to successfully develop an immunoassay cassette manufacturing line and achieve acceptable yields, could lead to an inability to cost-effectively satisfy customer orders and could have a material adverse effect on the Company's business, financial condition and results of operations.

Cholestech depends on single source suppliers for inputs to its manufacturing process. Cholestech's business will be harmed if these suppliers cannot provide supplies to Cholestech or experience problems with quality of supplied materials. Single source vendors currently provide subassemblies, components and raw materials used in the manufacture of Cholestech's products. Any supply interruption in a single source subassembly, component, or raw material could restrict Cholestech's ability to manufacture products until a new source of supply is identified and qualified. Cholestech 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 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 Cholestech or incompatible with Cholestech's manufacturing process, could interfere with our ability to manufacture products. Because Cholestech is a small customer of many of its suppliers and purchases its subassemblies, components and materials on a purchase order basis rather than pursuant to long term commitments, Cholestech's suppliers may not devote adequate resources to supplying Cholestech's 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 Cholestech's business.

If Cholestech is successful in growing sales, this success may be undermined if it cannot effectively manage the operational and management challenges of growth. If Cholestech is successful in achieving and maintaining market acceptance for the L-D-X System, Cholestech will be required to expand its operations, particularly in the areas of sales and marketing and manufacturing.

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

As Cholestech expands its operations, this expansion will likely result in new and increased responsibilities for management personnel and place significant strain upon Cholestech's management, operating and financial systems and resources. To accommodate any such growth and compete effectively, Cholestech will be required to implement and improve its information systems, procedures and controls, and to expand, train, motivate and manage its 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

29

30

CHOLESTECH CORPORATION

systems or to expand, train, motivate or manage employees 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.

Cholestech relies on distributors to sell its products, and has had difficulty in the past maintaining some distributor relationships. In order for Cholestech to increase revenues and achieve sustained profitability, we will have to maintain and expand our existing distribution relationships and develop new distribution relationships. Cholestech is dependent upon such distributors to assist it 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. We have in the past had problems maintaining relationships with our distributors to the pharmacy market. Distribution agreements with Amerisource and Bergen Brunswig Drug Company, both national distributors to the pharmacy market, were cancelled due to contractual performance issues. 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.

If third party reimbursement for use of Cholestech's 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. Cholestech will not be able to successfully market its products if the purchase and use of these products 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 Cholestech's products, our sales will be greatly reduced and our business will likely fail.

Reimbursement is currently not available for certain uses of Cholestech's products in particular circumstances. As a general rule, third party reimbursement is available if a physician has been involved in the decision to perform the test involving our products. For example, if a physician prescribes a drug that requires therapeutic monitoring, the use of our products in performing such tests will be reimbursable. In the health promotion market, use of our products for diagnostic screening in health promotion clinics is generally subject to reimbursement. However, diagnostic screening performed in corporate wellness programs and at fitness centers is likely not subject to

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

reimbursement.

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

- Third party payors are increasingly scrutinizing and challenging the prices charged for medical products and services.
- Healthcare providers are moving toward a managed care system in which such providers contract to provide comprehensive healthcare for a fixed cost per patient. Managed care

30

31

CHOLESTECH CORPORATION

providers are attempting to control the cost of healthcare by authorizing fewer elective procedures, such as uses of Cholestech's products for diagnostic screening.

- There is general uncertainty regarding what changes will be made in the reimbursement methods utilized by third party payors and how that will affect use of products such as Cholestech's. This uncertainty may deter healthcare providers from adopting the use of Cholestech Diagnostic Products.
- Cholestech believes that the 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 Cholestech.

Market acceptance of Cholestech's products in international markets is also dependent, in part, upon the availability of reimbursement within prevailing healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country and include both government sponsored healthcare and private insurance. Third party reimbursement and coverage may not be available or adequate in either the United States or international markets, and current reimbursement 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. See "Business -- Third Party Reimbursement."

There is a good likelihood that the healthcare system in the United States will undergo fundamental change, and there is no way to predict whether these changes will harm our business or how severe the effect will be. Political, economic and regulatory influences are pushing the healthcare industry in the United States to fundamental change. Cholestech anticipates that Congress, state legislatures and the private sector will continue to review and assess alternative healthcare delivery and payment systems. Potential approaches that have been considered include mandated basic healthcare benefits, controls on healthcare spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, the creation of large insurance purchasing groups, price controls and other fundamental changes to the healthcare delivery system. Legislative debate is expected to continue in the future, and market forces are expected to demand reduced costs. Cholestech cannot predict what impact the adoption of any federal or state health care

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

reform measures, future private sector reform or market forces may have on its business. There is the potential that changes in the healthcare system could have extremely negative effects on our business.

Cholestech's products are subject to multiple levels of government regulation that impose significant restrictions on Cholestech's business and could change in ways that are difficult to predict and that could be very damaging to our business. The manufacture and sale of Diagnostic Products, including the L-D-X System, are subject to extensive regulation by numerous governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies. Cholestech will not be able to commence marketing or commercial sales in the United States of any of the new tests it is developing until it receives required clearances and approvals. The process of obtaining required regulatory clearances and approvals is lengthy, expensive and uncertain. As a result, Cholestech's new tests under development, even if successfully developed, may never obtain such clearance or approval. Additionally, certain material changes to medical products already cleared or approved by are subject to further

31

32

CHOLESTECH CORPORATION

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. The loss of previously obtained clearances, or failure to comply with existing or future regulatory requirements, could prevent marketing of products affected, which would depress revenues and severely harm our business.

In addition, any future amendment of regulations or the promulgation of additional regulations impacting Cholestech's products could prevent Cholestech from marketing the L-D-X System. Regulatory changes could hurt our business by increasing burdens on our products. Regulatory changes could also harm our business by reducing regulatory requirements and burdens faced by competitive products, certain competitive advantages of the L-D-X System's waived status could be reduced or eliminated.

Currently, Cholestech's Diagnostic Products are regulated in the United States by the Food and Drug Administration. The L-D-X Analyzer and all existing test cassettes required clearance by the Food and Drug Administration. Food and Drug Administration clearance or approval of products such as Cholestech's can be obtained by either of two processes:

- The 510(k) clearance process, which generally takes from four to twelve months from the date of submission to obtain, but may take longer.
- The pre-market approval process, which is a much 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 from the date on which the application is accepted for filing, but may take significantly longer.

If Cholestech's 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 the Company's products and those of its competitors is also affected by federal and state regulations, which provide for regulation of

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

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 Improvements Act of 1976. The L-D-X Analyzer and Cholestech's total cholesterol, HDL (high density lipoproteins), Triglycerides and glucose tests in any combination have been classified as waived from the application of many of the requirements under the Clinical Laboratory Improvements Act. Cholestech believes that this waived classification is critical for its products to be successful in their markets. Cholestech's new tests, including the ALT test cassette, may not qualify for waived classification. Any failure of the new tests to obtain waived status under the Clinical Laboratory Improvements Act will severely limit 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 revenues, which would severely harm our business.

The European Union has promulgated rules that require that devices such as those developed, manufactured and sold by Cholestech receive the right to affix the CE mark, a symbol of adherence to applicable European Union directives. Cholestech has completed all the testing necessary to comply with applicable regulations to currently be eligible for self-certification and currently has the right, as self-certified under the product testing requirements, to affix the CE

32

33

CHOLESTECH CORPORATION

mark to its products. Cholestech's products will be covered by the In Vitro Diagnostics Directives that have not yet been officially published or adopted. Cholestech may lose its self-certified status if it is not successful in meeting the European Union certification requirements. Failure to receive the right to affix the CE mark may prohibit Cholestech from selling its products in European Union member countries. This would result in lost sales and market share and significant financial harm to our business.

Cholestech's manufacturing processes are subject to regulation and, if we do not comply with these regulations, our manufacturing could be suspended, resulting in unfilled orders, customer dissatisfaction, and lost sales, revenues and market share. Cholestech's manufacturing processes, as well as, 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 these regulations could result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to grant pre-market clearance or pre-market approval for devices, withdrawal of approvals and criminal prosecution. Any of these could harm our business. Cholestech and our contract manufacturers are subject to federal, state and foreign regulations regarding the manufacture of healthcare products and diagnostic devices, including:

- Quality System Records ("QSR"), which requires the company to maintain a quality system consistent with FDA regulations.
- ISO9001/EN46001 requirements, which is an industry standard for maintaining quality standards and assuring conformance to said standards.
- Other foreign regulations and state and local health, safety and

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

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 the Company's products. Cholestech may be required to incur significant costs in the future in complying with manufacturing and environmental regulations.

Our business depends on our ability to protect our proprietary technology through patents and other means, which may not be successful or may require costly litigation to enforce. If our protective measures are not successful our competitors will be able to use our technology to compete with us, and if we have to enforce our protective measures we may have to divert time and money from operating our business. The Company's ability to compete effectively will depend in part on its ability to develop and maintain the proprietary aspects of its technology and operate without infringing the proprietary rights of others. The Company has nine United States patents and has filed patent applications relating to its technology internationally under the Patent Cooperation Treaty and individual foreign patent applications. 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.

33

34

CHOLESTECH CORPORATION

- Competitors, many of which 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. Cholestech 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.
- An adverse determination in litigation or interference proceedings to which Cholestech 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.

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

If third party sponsorship of WellCheck testing service is eliminated or reduced, our revenues will be greatly reduced and our business may fail. WellCheck derives the majority of its revenue from third parties using the Company's testing service 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 service and our revenue will be greatly reduced and our business will likely fail.

We will need to locate an adequate number of testing venues for the WellCheck testing service. In order for the testing service to be successful, the Company will need to maintain the current number of testing sites and find a greater number of locations, and more diverse venues to perform consumer testing. The Company will need to convince operators of the venues there will be economic benefits from the testing service. If the number of testing sites do not increase or are reduced, Cholestech could be harmed financially.

If third party sponsorship of the WellCheck.com web site is eliminated or reduced, our revenues will be greatly reduced and our business may fail. The WellCheck.com web site anticipates all revenues will be derived from third parties advertising, sponsorship, or offering services to web site members. If third parties decline to participate, or fees are significantly lower than estimated, revenue will be greatly reduced and our business will likely fail.

The Company will have to maintain a significant active membership in the WellCheck.com web site. In order to generate expected revenues we will need to demonstrate to web site sponsors the number of visitors, and the number or repeat visitors. If web site membership does not reach the required level or use of the web site declines, revenues will be eliminated or significantly reduced.

34

35

CHOLESTECH CORPORATION

We will need to effectively implement and use the TEAMS software, which transfers consumer information from test locations to the WellCheck web site. In order to meet consumer expectations of timely feed back, the TEAMS software will be the conduit, which will transfer the large number of consumer test results in a timely manner. If the TEAMS software is not available, manual data entry by the company or the customer will be required. The additional time and inconvenience could reduce the number of people willing to become a member of the web site. If customers are not provided an efficient method of accessing the data on the web site membership can be eliminated or significantly reduced, which could harm Cholestech financially.

The Company will need to market the use of TEAMS software to sponsors of testing programs. TEAMS software is a proprietary tool to transfer large amounts of information from testing sites to our web site. We must be able to convince sponsors it is a cost effective method, and will improve the testing experience for consumers. If we are unable to have event sponsors pay for the use of TEAMS, we would be unable to recover the cost of developing and maintaining TEAMS, which could significantly reduce profits.

35

36

CHOLESTECH CORPORATION

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

ITEM 3 QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk for changes in interest rates relates primarily 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 at December 29, 2000. Securities held are subject to interest rate risk and will fall in value if market interest rates increase. We do not believe near-term changes in interest rates should not materially adversely affect our financial position, results of operations or cash flows.

36

37

CHOLESTECH CORPORATION

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

On February 5, 1999, a complaint entitled *Ree v. Pinckert, et al.*, No.C99-0562 (MMC) was filed in the United States District Court for the Northern District of California. The Action is a putative classaction and the complaint alleges that Cholestech and an officer, Mr. Pinckert, violated the federal securities laws by misleading investors during the time period of July 30, 1997 - June 26, 1998, concerning the Company's business and its future prospects. On June 24, 1999, plaintiffs filed an amended complaint, which expanded the putative class period to June 28, 1996, through June 26, 1998. The amended complaint's substantive allegations and purported causes of action remain based on allegations that the Company misled shareholders concerning the Company's business and its future prospects. The complaint does not specify alleged damages. On September 20, 1999, defendants filed a motion to dismiss plaintiff's amended complaint. On March 28, 2000, the court granted defendant's motion to dismiss pursuant to rule 12(B)(6) with leave for plaintiffs to amend. The plaintiffs have filed an amended complaint. The Company intends to defend the case vigorously. The Company does not believe that the defendants in the class action 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 lawsuit will be resolved in the Company's favor. The action is in its preliminary stages and a trial date has not been set.

In September, 2000, the Company was served with a complaint, No. Ei/Ti ROCH 04002, was filed in Vienna, Austria by Roche Diagnostics on January 13, 2000. seeking a cease and desist order barring the Company, and a distributor, Euromedix, from distributing HDL assay single-use test cassettes in Austria. The complaint alleges that Cholestech violated a Roche European patent for HDL. The Company is in the process of responding to the complaint. At this point in time no schedule has been set regarding court activity. There can be no assurance as to whether the plaintiffs will take any additional action, or whether any additional action will be resolved in the Company's favor.

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 the Company, and two distributors, Healthcare Solutions and Euromedix, from distributing HDL assay single-use test cassettes in Switzerland. The complaint alleges that Cholestech violated a Roche European patent for HDL. The Company has filed its 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 the Company's legal fees. The plaintiff has appealed the court ruling and it will be several weeks before we are notified of the case details. There

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

can be no assurance as to whether the plaintiffs will take any additional action, or any additional action be resolved in the Company's favor.

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

37

38

CHOLESTECH CORPORATION

believes the suit is without merit and intends to defend the case vigorously. Therefore, the Company does 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 the Company's favor.

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.

38

39

CHOLESTECH CORPORATION

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

- (a) Exhibits:
 - 27.1 Financial Data Schedule

39

40

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 2/8/01 /s/ Warren E. Pinckert II

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

Edgar Filing: CHOLESTECH CORPORATION - Form 10-Q

/s/ Andrea J. Tiller

Andrea J. Tiller
Vice President of Finance and Chief
Financial Officer
(Principal Financial and Accounting Officer)

40

41

CHOLESTECH CORPORATION

EXHIBITS INDEX

Exhibits:

27.1 Financial Data Schedule

41