

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

CHOLESTECH CORPORATION
Form 10-K
June 25, 2001

1

SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED MARCH 30, 2001

OR

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

FOR THE TRANSITION PERIOD FROM _____ TO _____ .

COMMISSION FILE NUMBER: 000-20198

CHOLESTECH CORPORATION
(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

CALIFORNIA
(STATE OR OTHER JURISDICTION OF
INCORPORATION OR ORGANIZATION)

94-3065493
(I. R. S. EMPLOYER
IDENTIFICATION NUMBER)

3347 INVESTMENT BOULEVARD
HAYWARD, CALIFORNIA 94545
(510) 732-7200
(ADDRESS, INCLUDING ZIP CODE, AND TELEPHONE NUMBER, INCLUDING AREA CODE, OF
REGISTRANT'S PRINCIPAL EXECUTIVE OFFICES)

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT: NONE

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT:
COMMON STOCK, NO PAR VALUE
SERIES A PARTICIPATING PREFERRED STOCK, NO PAR VALUE
(TITLE OF CLASS)

Indicate by check mark whether the registrant (1) has filed all reports
required to be filed by Section 13 or 15(d) of the Securities Exchange Act of
1934 during the preceding 12 months (or for such shorter period that the
registrant was required to file such reports), and (2) has been subject to such
filing requirements for the past 90 days. Yes [X] No []

Indicate by check mark if disclosure of delinquent filers pursuant to Item
405 of Regulation S-K is not contained herein, and will not be contained, to the

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. []

The aggregate market value of the voting stock held by non-affiliates of the registrant, based on the closing sale price of the common stock on March 30, 2001 as reported on the NASDAQ National Market, was approximately \$46,199,000. Shares of common stock held by each officer and director and by each person who owns 5% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of June 20, 2001, the registrant had outstanding 12,112,219 shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant has incorporated by reference into Part III of this Annual Report on Form 10-K portions of its Proxy Statement for the 2001 Annual Meeting of Shareholders to be held August 16, 2001.

2

CHOLESTECH CORPORATION

FORM 10-K
FOR THE YEAR ENDED MARCH 30, 2001

TABLE OF CONTENTS

| | PAGE |
|---|------|
| | ---- |
| PART I | |
| Item 1. Business..... | 1 |
| Item 2. Properties..... | 18 |
| Item 3. Legal Proceedings..... | 18 |
| Item 4. Submission of Matters to a Vote of Security Holders..... | 19 |
| PART II | |
| Item 5. Market for Registrant's Common Equity and Related Stockholder Matters..... | 20 |
| Item 6. Selected Consolidated Financial Data..... | 21 |
| Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations..... | 23 |
| Item 7A. Quantitative and Qualitative Disclosures About Market Risk..... | 42 |
| Item 8. Financial Statements and Supplementary Data..... | 43 |
| Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure..... | 43 |
| PART III | |
| Item 10. Directors and Executive Officers of the Registrant..... | 44 |
| Item 11. Executive Compensation..... | 44 |
| Item 12. Security Ownership of Certain Beneficial Owners and Management..... | 44 |
| Item 13. Certain Relationships and Related Transactions..... | 44 |

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

PART IV

| | |
|--|----|
| Item 14. Exhibits, Financial Statements Schedules and Reports on Form 8-K..... | 44 |
| Signatures..... | 48 |

i

3

PART I

This Annual Report on Form 10-K, the exhibits hereto and the information incorporated by reference herein contain "forward looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended, and such forward looking statements involve risks and uncertainties. When used in this Report, the words "expect," "anticipate," and "estimate" and similar expressions are intended to identify forward looking statements. Such statements are subject to risks and uncertainties that could cause actual results to differ materially from those projected. These risks and uncertainties include those discussed below and those discussed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" or incorporated by reference herein. Cholestech Corporation ("we", "us" or "Cholestech") undertakes no obligation to publicly release any revisions to these forward looking statements to reflect events or circumstances after the date this Report is filed with the Securities and Exchange Commission or to reflect the occurrence of unanticipated events.

ITEM 1. BUSINESS

GENERAL

In the past fiscal year, we engaged in three business activities:

- Diagnostic Products -- which develops, manufactures and markets our Cholestech L-D-X(R) System (the "L-D-X System") which performs near-patient diagnostic tests that assist in assessing the risk of heart disease, certain liver diseases, and in the monitoring of therapy to treat those diseases.
- WellCheck(TM) -- which conducts cholesterol testing within the United States that assesses the risk of heart disease and assists in the monitoring of therapy to treat that diseases.
- WellCheck.com -- which provides interactive tools to consumers through the Internet to better assess the risk of heart disease and to monitor and motivate personal health management of that disease.

Diagnostic Products currently manufactures and markets the L-D-X System, including the L-D-X Analyzer and a variety of single-use test cassettes, in the United States and internationally. The L-D-X System allows health care providers to perform individual tests or combinations of tests with a single drop of blood from a fingerstick within five minutes. Our current products measure and monitor blood cholesterol, related lipids, glucose and liver function, and are used to test patients at risk of or suffering from heart, diabetes or liver disease.

WellCheck currently provides cholesterol and related testing services and education to the general public using the L-D-X System and creates opportunities for sales of test cassettes manufactured by our Diagnostic Products business. WellCheck's professionals provide high quality services and offer test event expertise to both event sponsors and consumers. As part of our testing services, we utilize our proprietary Test Event Activity Management System ("TEAMS") technology which automates registration, data acquisition and information

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

management at promotional, corporate wellness and other consumer testing events and provides consumers with a personalized risk assessment for heart disease. Substantially all of WellCheck's revenue is derived from promotional programs with major pharmaceutical companies marketing lipid-lowering statin drugs. We believe an opportunity exists to further expand our testing services business in the promotional, corporate wellness, retail markets and other convenient venues which broaden consumer access to testing while assisting consumer product companies, such as pharmaceutical companies, in customer acquisition. Our goal is to develop the first nationwide consumer testing services company for chronic diseases.

We launched WellCheck.com in October 1999 to develop website content and our TEAMS technology to provide consumers with interactive tools to learn about and manage heart disease. Based on our determination that adequate sponsor funding for a retail-oriented, chronic disease management model roll out was unavailable at present, we refocused on expanding our activities in the promotional and corporate wellness markets. As a result, our WellCheck.com business unit and its consumer-oriented website have been repositioned as a technology support tool for our WellCheck testing business. In the fourth quarter of fiscal

1

4

2001, we recorded a non-cash, non-recurring charge of \$1.96 million to reflect the impairment of certain intangible assets associated with the development of WellCheck.com's website and database.

More recently we merged WellCheck.com into WellCheck. We intend to operate and manage WellCheck and WellCheck.com as one business segment in fiscal 2002 and beyond.

MARKET OVERVIEW

We believe the market for our products and services exists where the management of heart disease meets the growing consumer trend for personal health management.

Heart disease consists of long lasting or frequently recurring illnesses that, due to their protracted and serious nature, are costly to treat and monitor. High cholesterol is a significant contributing factor to cardiovascular diseases, which remain the number one cause of death in America and kill more people than the next seven diseases combined. Heart disease is also the leading cause of death among diabetics.

- The American Heart Association estimates that more than 61 million people suffer from some form of cardiovascular disease, which is the leading cause of death of adults in the United States and resulted in over 949,000 deaths in 1998.
- Based on the evidence of scientific studies, the National Cholesterol Education Program ("NCEP") expert panel on the detection, evaluation and treatment of high blood cholesterol in adults and the National Institutes of Health ("NIH") in May 2001 issued new guidelines which are expected to substantially increase the number of Americans being treated for high cholesterol. Numerous research studies substantiate that reducing high cholesterol levels, primarily LDL levels, significantly reduces the risk of a coronary event. The number of Americans following therapeutic lifestyle changes is expected to increase from 52 million to 65 million and the number of prescribed cholesterol lowering drugs is projected to increase from 13 million to approximately 36 million.

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

- According to the new NIH guidelines, it is estimated that approximately 101 million, or one out of every two adult Americans, should be treated for the chronic condition of high cholesterol, which has been linked by conclusive evidence to cardiovascular disease.
- Diabetes is estimated to afflict approximately 16 million people in the United States, over a third of whom have not yet been identified as being diabetic.
- Heart disease is the leading cause of diabetes-related deaths. Adults with diabetes have heart disease death rates approximately two to four times higher than adults without diabetes.

The current healthcare system in the United States, while historically successful in treating acute conditions, was not designed to adequately serve the growing need for preventive healthcare and the management of chronic conditions such as heart disease. In addition, over 42 million Americans do not have health insurance. Both of these factors are driving a growing trend towards personal health management, which we believe we are uniquely positioned to service by providing practical, economical and efficient tools and information to address a widespread, growing need for convenient, accurate cholesterol testing as a part of a disease management program which may reduce costs and improve treatment. Our cost effective technologies:

- identify at risk patients via convenient testing venues;
- screen for heart disease by identifying individuals with elevated cholesterol levels;
- monitor the ongoing condition of people with heart disease whose treatment programs may involve long-term, complex drug therapies; and
- enable consumers to take a more active role in their personal health management.

2

5

MARKET OPPORTUNITY FOR SPONSORS AND PARTNERSHIPS

Many consumer product companies are interested in reaching consumers who may potentially be at risk for elevated cholesterol and therefore more likely to purchase their products. Because our technology and services are designed to meet the needs of consumers who wish to personally manage their cardiovascular health, we are an attractive partner to these other companies.

Pharmaceutical companies have focused considerable resources on developing drugs for the treatment of heart disease, diabetes and other chronic diseases. While drug therapy is necessary for the overall treatment of chronic diseases, diagnostic screening and the proper monitoring of therapy are also important in both an effective program to manage chronic diseases and patient education. Widespread diagnostic screening for chronic diseases helps in the early identification of patients who may benefit from drug therapy. Effective administration of drug therapies often requires careful therapeutic monitoring of a drug's impact on body chemistry to ensure proper drug dosages, monitor improvement and reduce the risk of side effects. Moreover, ongoing compliance with drug therapy is necessary for effective treatment and reduces the risk to patients of adverse side effects.

In addition, a wide range of non-pharmaceutical companies have developed products which target consumers with cholesterol problems or interests. These include the manufacturers of food, vitamins and other non-regulated

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

nutraceutical products which have features and benefits designed to reduce cholesterol.

Some of the emerging issues in healthcare are the increase of self-insured employers and the increase of health and quality-of-life programs offered by employers to their employees. We are also well positioned to help these companies provide programs which screen their employees for cardiovascular risk and support cardiovascular health programs within the employer's provider plan.

We believe we are well positioned to meet the needs of potential sponsors and partners. Our unique technology, easy and convenient service and interactive tools create a personal interaction with the consumer, which may be expanded to include other related products and services.

MARKET SEGMENTS

We specifically target our products and services at markets outside of traditional hospital or clinical laboratories. These markets include:

- physician office laboratories, which are operated by physicians or groups of physicians. The physician office laboratory market consists of approximately 96,000 sites that are registered with the Health Care Finance Administration, approximately 41,000 of which are registered to perform only tests that have been waived under the Clinical Laboratory Improvement Act ("CLIA waived");
- health promotion sites, which include a variety of locations such as corporate wellness programs, fitness centers, health promotion service providers, community health centers, public health programs, the United States military and other independent screeners; and
- consumer events such as promotional sporting and social events and retail venue events.

OUR STRATEGY

Our objective is to extend the technological capabilities and performance of our core Diagnostic Products business to meet the anticipated need for widespread community based testing for heart disease. We developed our WellCheck testing business to integrate our traditional Diagnostic Products business with a testing service to meet this projected need. By combining diagnostic products with testing services we hope to achieve both financial and competitive advantages due to increased market penetration, expanded sales of test cassettes manufactured by our Diagnostic Products business and improved disease management therapy and compliance.

3

6

The components of our strategy related to our Diagnostic Products business include:

- Increase Market Penetration. We intend to further penetrate the physician office laboratory and health promotion markets by increasing the number of installed L-D-X Analyzers both domestically and internationally. We have implemented marketing and related programs to increase awareness of the advantages of the L-D-X System among health care providers, third party payors and consumers. In addition, we have entered into strategic relationships with major pharmaceutical companies to promote preventive care testing with the L-D-X System as an important component of the management of cholesterol-related disease.

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

- Expansion of Testing Technology. We intend to develop a more effective and efficient platform technology and expand our range of multi-element, single-use, disposable cassettes to address additional diagnostic tests to screen for and manage chronic disease, such as our alanine aminotransferase ("ALT") test, which was waived under CLIA by the United States Food and Drug Administration in April 2001 and will assist in monitoring the impact and potential adverse side effects on the liver from lipid lowering and other therapies.
- Expansion of Cassette Usage. We intend to increase the sale of single-use test cassettes through additional placement of L-D-X Analyzers, development of new diagnostic tests and broadening the testing venues offered by our WellCheck business.
- Expansion of Manufacturing Capabilities and Efficiencies. We intend to expand our manufacturing capacity by completing a third line for the manufacture of cassettes, which is currently in a pre-production validation stage and should be in full operation in July 2001. Additionally, we will seek to introduce new manufacturing technologies to improve the key performance attributes of our manufacturing process, including quality, yields and efficiencies.
- Expansion of Distribution Relationships. We intend to augment our sales and marketing efforts by continuing to establish relationships with select third party distributors to strategically access and service our markets in the United States and internationally.

The components of our strategy related to our WellCheck business include:

- Broaden Consumer Testing. We intend to broaden the geographic coverage of our WellCheck testing services by furthering our expansion in the promotional and corporate wellness markets, expanding into the retail market and other convenient venues designed to increase consumer access and acquiring additional regional testing companies. In addition, an expansion of our consumer testing services will create opportunities for sales of test cassettes manufactured by our Diagnostic Products business.
- Improve Consumer Access to Testing. We intend to focus on testing outside of clinical or hospital laboratories by providing products and services that improve people's access to cholesterol-related disease risk assessment and management. We believe that more convenient testing will increase the frequency of diagnostic testing and may lead to earlier identification of patients at risk of or suffering from cholesterol-related diseases.
- Enhance TEAMS Technology. We have developed, and intend to enhance, our software for test event activity management, which is a proprietary interactive testing program designed to facilitate the operation of a cholesterol-related disease testing event using the L-D-X System by providing data acquisition and patient information management to both the event sponsor and the consumer.
- Further Develop Strategic Relationships and Business Partnerships. We have established and intend to further develop strategic relationships to improve penetration of our target markets. In particular, we intend to further our alliances with major pharmaceutical companies and other companies interested in health promotion to position our products and services as the preferred tools for the personal health management for cholesterol-related diseases. We also intend to provide companies interested in targeting consumers who are at risk for cholesterol-related diseases a more effective, direct means of interacting with consumers. For example, we currently have two contracts to provide screening for a

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

major pharmaceutical manufacturer through our relationship with GMR Marketing, an Omnicom

4

7

DAS agency which is a leader in sports, mobile, music/entertainment, ethnic, and lifestyle marketing and produces major events on a nationwide basis on behalf of its clients.

We merged WellCheck.com into WellCheck. We intend to leverage the synergies of the two segments into a more efficient business. The merger became effective in June 22, 2001.

PRODUCTS AND PRODUCTS UNDER DEVELOPMENT

We offer a variety of products and services in each of our businesses, including products currently under development.

DIAGNOSTIC PRODUCTS

Diagnostic Products manufactures, markets and develops diagnostic testing technology which facilitates the performance of near patient diagnostic testing to assist in assessing the risk of certain cholesterol-related diseases, certain liver diseases, and in the monitoring of therapy to treat those diseases. Diagnostic Products currently manufactures and markets the L-D-X System, including the L-D-X Analyzer and a variety of single-use test cassettes, in the United States and internationally.

Overview of the Cholestech L-D-X(R) System

The L-D-X System is an easy to use, multi-element testing system consisting of a telephone-sized analyzer, a variety of single-use, credit card-sized test cassettes, a printer and accessories. The L-D-X System allows health care providers to perform individual tests or combinations of tests with a single drop of blood within five minutes. No special training is required to operate the L-D-X System, and the sample does not need to be pre-treated. To run a test, the health care provider pricks the patient's finger, transfers a drop of blood to the cassette's sample well, inserts the cassette into the L-D-X Analyzer's cassette drawer and presses the "run" button. All further steps are performed by the L-D-X System, which produces results comparable in accuracy to results from larger, more expensive bench top and clinical laboratory instruments that are not CLIA waived.

The design of the L-D-X System incorporates as much proprietary technology as possible into the test cassettes and maintains the L-D-X Analyzer as a platform that can be easily adapted as new tests and other product upgrades are introduced. As health care providers perform different tests, the encoding on the cassette's magnetic strip communicates test specific and calibration information to the L-D-X Analyzer. Changes that cannot be captured on the cassette's magnetic strip can be accomplished by changes to the L-D-X Analyzer's removable read only memory software pack. This flexible design enables health care providers to perform a variety of tests using the same L-D-X Analyzer and to take advantage of new tests and other product upgrades without having to purchase a new L-D-X Analyzer.

The L-D-X System includes software that performs cardiac risk assessments using risk factor parameters developed from the Framingham study, a long term study of cholesterol levels and cardiovascular disease.

The L-D-X Analyzer

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

The L-D-X Analyzer is a four-channel, reflectance photometer that measures the amount of light reflected from the reaction surfaces of a test cassette and incorporates a microprocessor with built-in software. The L-D-X Analyzer contains a drawer for insertion of the cassette, three buttons for user activation and a liquid crystal display to present the test results. Using the information and instructions encoded on the cassette's magnetic strip, the L-D-X Analyzer's built-in microprocessor regulates the reaction conditions, controls the optical measurements of analyte concentrations on the cassette's reaction pads, executes the required calculations and, within five minutes, displays the results on the liquid crystal display. The results are displayed as a numerical value of the level of the analyte tested and can be transferred to a printer, computer or computer network.

The software calculates the numeric values of the test results and is contained in a removable read only memory software pack mounted in an access well on the bottom of the L-D-X Analyzer. We will continue to

5

8

upgrade the software as new products are developed, allowing health care providers to easily replace the existing read only memory pack with a new pack containing upgraded software. The L-D-X Analyzer, along with a printer, accessories and starter pack, comprises a L-D-X System and currently has a domestic list price of \$1,995.

Cassette Products

Our line of single-use test cassettes for the L-D-X System incorporates patented and licensed technology for distributing precisely measured plasma to multiple reaction pads for simultaneous testing. Each cassette has three parts: a main body that contains the sample well into which the blood sample is dispensed, a reaction bar where plasma is transferred for analysis and a magnetic strip encoded with test instructions and lot specific calibration information for the various chemistries on the reaction pads. Capillary action draws a drop of blood through a separation medium within the cassette, stopping the cellular components of the blood while transferring a small volume of plasma to the cassette's reaction pads. When the plasma contacts the reaction pads, the dry chemistry reacts with the analytes in the plasma, producing color. The intensity of color developed indicates the concentration of the analytes in the plasma. The magnetic strip contains information needed by the L-D-X Analyzer to convert the reflected color reading into a concentration level for the accurate measurement of the analytes being tested. This automatic process means that the health care provider does not have to interpret any color reaction, relate a reading to a separate chart or input calibration information. Our available test cassettes range in current domestic list price from \$3.95 to \$10.95 per cassette and include up to four tests per cassette.

The following table summarizes our current products and products under development:

| PRODUCT ----- | REGULATORY STATUS(1) ----- |
|------------------------------------|-------------------------------|
| INSTRUMENT | |
| L-D-X Analyzer | FDA cleared; CLIA waived |
| CASSETTE PRODUCTS | |
| Current | |
| Total cholesterol | FDA cleared; CLIA waived |
| Total cholesterol and High density | FDA cleared; CLIA waived |

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

| | |
|--|--------------------------|
| lipoproteins | |
| Lipid Profile | FDA cleared; CLIA waived |
| (Total cholesterol/High density lipoproteins/ Calculated low density lipoproteins/Triglycerides) | |
| Total cholesterol and Glucose | FDA cleared; CLIA waived |
| Total cholesterol/High density lipoproteins/Glucose | FDA cleared; CLIA waived |
| Lipid Profile plus Glucose | FDA cleared; CLIA waived |
| Alanine Aminotransferase (AST) | FDA cleared; CLIA waived |
| Under Development (2) | |
| Aspartate Aminotransferase (ALT) | Not filed or applied |
| In Feasibility Studies (3) | |
| Glycated Hemoglobin | Not filed or applied |
| Direct high density lipoproteins | Not filed or applied |
| Direct low density lipoproteins | Not filed or applied |
| High sensitivity C-Reactive Protein (CRP) | Not filed or applied |

-
- (1) "FDA" means the United States Food and Drug Administration; "FDA cleared" means the product has received clearance pursuant to Section 510(k) of the Food, Drug and Cosmetics Act of 1938, as amended. "CLIA waived" means the Food and Drug Administration has granted our application to classify the product as having waived status with respect to the Clinical Laboratory Improvement Act.
 - (2) Products under development are those that have completed the feasibility phase of the commercialization process and have begun the development phase. During the development phase, manufacturing processes are developed and defined, initial lots are made using those manufacturing processes and performance

6

9

against product specifications is demonstrated. The products under development are then transferred to manufacturing prior to launch.

- (3) Products in the feasibility phase of our commercialization process are studied to determine the compatibility of the reagents with the single use test cassette, and preliminary data is generated to indicate if the reagents can perform to preliminary specifications.

Current Cassette Products

Our current cassette products are designed to measure and monitor blood cholesterol, related lipids, glucose and alanine aminotransferase. Lipids travel in the blood within water-soluble particles called lipoproteins.

- Total Cholesterol. This stand-alone test for measuring total cholesterol ("TC") was our first test, developed in conjunction with National Cholesterol Education Panel guidelines issued in 1988.
- Total Cholesterol and High Density Lipoproteins Panel. The TC and high density lipoproteins ("HDL") panel addresses current National Cholesterol Education Panel guidelines regarding the nonfasting screening for the risk of cardiovascular disease by testing both TC and HDL. HDL particles circulate in the blood and can pick up cholesterol from arteries and carry it to the liver for elimination from the body. HDL is sometimes called "good cholesterol" because of this function.

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

We believe the TC and HDL panel is particularly useful in diagnostic screening applications. This panel also calculates the ratio of TC to HDL, a recognized measure of cholesterol induced cardiac risk.

- Lipid Profile. We offer a lipid profile cassette, which directly measures TC, HDL and triglycerides. In addition, the lipid profile cassette calculates estimated values for LDL and the ratio of TC to HDL. The development of cardiovascular disease has been associated with three lipoprotein abnormalities: high levels of LDL, high levels of very low density lipoproteins ("VLDL") and low levels of HDL. LDL, the major carrier of cholesterol, and VLDL, a major carrier of triglycerides in the blood, have been shown to be associated with deposits of plaque on the arterial wall. High levels of triglycerides can also lead to development of such plaque. Accumulation of this plaque leads to a narrowing of the arteries and increases the likelihood of cardiovascular disease. The lipid profile cassette thus performs multiple tests in the diagnostic screening and ongoing therapeutic monitoring of individuals who have high LDL levels or who exhibit two or more other cardiovascular disease risk factors. National Cholesterol Education Panel guidelines recommend that health care providers perform three lipid profiles, each one week apart, before initiating lipid lowering drug therapy.
- Total Cholesterol and Glucose Panel, Total Cholesterol/High Density Lipoproteins/Glucose Panel and Lipid Profile plus Glucose Panel. Recognizing the relationship between diabetes and abnormal lipid levels, we developed a glucose test for the L-D-X System and combined it with each of its three lipid related test panels. The resulting panels provide input used in the diagnostic screening and therapeutic monitoring of patients with diabetes, whether or not they are aware they are diabetic, as well as of individuals who may be at risk for cardiovascular disease.
- Alanine Aminotransferase. Patients undergoing certain drug therapies must be monitored for increases in certain enzymes that are associated with liver damage. The availability of an alanine aminotransferase ("ALT") test combined with our lipid profile will allow health care providers to monitor both the impact of and potential adverse side effects on the liver from lipid lowering and diabetic therapies. We received 510(k) clearance to market ALT in September 1999 and received CLIA waived status in April 2001.

7

10

Cassette Products Under Development

Products listed under development are undergoing optimization of design, performance testing, scale up, clinical trials, regulatory submissions and transfer to production.

- Aspartate Amino Transferase. Patients undergoing certain drug therapies must be monitored for increases in certain enzymes that are associated with liver damage. The availability of an aspartate amino transferase ("AST") test in conjunction with the our ALT test would allow health care providers to monitor both the impact of and potential adverse side effect on the liver from lipid lowering and diabetic therapies. This cassette product has completed the feasibility phase and is starting the development process.

Cassette Products in Feasibility Studies

We are in various stages of feasibility studies for new cassettes that

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

would expand our product line for diagnostic testing. We may develop additional tests depending on the progress of our existing development efforts and available resources.

- Glycated Hemoglobin. Glycated hemoglobin (hemoglobin A1c) measurement is an immunoassay test used by health care providers to assess a diabetic's long-term compliance with prescribed diet and insulin usage. A relatively high percentage of glycated hemoglobin to glucose indicates poor patient compliance, which can lead to severe health problems. The American Diabetes Association recommends at least semi-annual measurement of glycated hemoglobin for all individuals with diabetes.
- Direct High Density Lipoproteins. The direct HDL cholesterol test is able to measure HDL cholesterol directly in the patient sample without the need to remove the non-HDL cholesterol lipoproteins from the sample before analysis, which takes place in the current HDL cholesterol test on the L-D-X cassette. The direct HDL cholesterol test represents the next generation of measurement of HDL cholesterol and is planned to replace the current HDL cholesterol test.
- Direct Low Density Lipoproteins. The direct low density lipoproteins ("LDL") cholesterol test permits the direct measurement of LDL cholesterol in a patient sample. The calculated LDL cholesterol is subject to a number of limitations including the need for a fasting sample. The direct LDL cholesterol test should be reimbursable, whereas the calculated test is not reimbursable.
- High Sensitivity C-Reactive Protein. The high sensitivity C-reactive protein ("CRP") test measures, by immunoassay, the amount of CRP present in a patient sample. CRP is an independent risk factor for heart disease and is useful in predicting the risk of future cardiovascular events.

WELLCHECK (TM)

WellCheck provides easy and economic testing for heart disease in venues across the United States that are convenient to consumers.

Overview of WellCheck Testing Services

WellCheck currently provides cholesterol and related testing services and education to the general public using the L-D-X System and creates opportunities for sales of test cassettes manufactured by our Diagnostic Products business. WellCheck's professionals provide high quality services and offer test event expertise to both event sponsors and consumers. As part of our testing services, we utilize our proprietary TEAMS technology which automates registration, data acquisition and information management at promotional, corporate wellness and other consumer testing events and provides consumers with a personalized risk assessment for heart disease. Substantially all of WellCheck's revenue is derived from promotional programs with major pharmaceutical companies marketing lipid-lowering statin drugs. We believe an opportunity exists to further expand our testing services business in the promotional, corporate wellness, retail markets and other convenient venues which broaden consumer access to testing while assisting consumer

product companies, such as pharmaceutical companies, in customer acquisition. Our goal is to develop the first nationwide consumer testing services company for chronic diseases.

We intend to seek opportunities to expand our WellCheck business through

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

both internal development and the assessment of additional acquisition or partnership candidates to add more specific regional coverage to WellCheck's testing services.

In addition, we continue to augment the capabilities of our TEAMS software, a proprietary interactive testing program designed to facilitate the operation of a cholesterol-related disease testing event using the L-D-X System. TEAMS is used to capture participants' registration, self health assessment and results from the L-D-X System while supporting event logistic processes. Information is processed following National Cholesterol Education Program guidelines. Individual participant reports, created for one to one education and consulting with a WellCheck health promotion associate to assess an individual's results and potential risk of heart disease based on the long-established Framingham Study, can be provided immediately at the test site.

STRATEGIC RELATIONSHIPS

We have established and continually seek to develop strategic relationships, which we believe will enhance the commercialization of our products. In particular, we intend to enter into additional strategic alliances with major pharmaceutical and other companies to enhance our market positioning and our product offerings. Our current strategic relationships are described below.

GMR Marketing Inc.

We have entered into numerous promotional programs with GMR Marketing Inc., a division of Omnicom ("GMR") in relation to the cholesterol-lowering statin drug "Lipitor." These have included:

- "Screen Test For Health". GMR sponsored two WellCheck mobile screening units to screen consumers for elevated cholesterol and cardiovascular disease at promotional sporting events across the United States in 2000. Three additional units have been added to the program and will conduct testing through calendar 2001.
- "Tune Up For Life". GMR sponsored a WellCheck mobile screening unit to provide men's health assessments across the United States in 2000 and 2001.

Physician Sales and Service, Inc.

We entered into a distribution partnership with Physician Sales and Service, Inc. in 1996 for the distribution of our diagnostic products to physician offices. Physician Sales and Service has been our largest single customer for the last three years, contributing \$6.1 million of revenue in fiscal 2001, \$4.6 million in fiscal 2000 and \$3.4 million in fiscal 1999.

Merck and the American Pharmaceutical Association

In January 1996, the American Pharmaceutical Association announced Project ImPACT (Improve Persistence And Compliance to Therapy), a joint effort between the American Pharmaceutical Association, Merck & Co., Inc. ("Merck") and our company (the "Project"). The goal of the Project was to demonstrate the ability of pharmacists to improve patient outcomes by expanding the pharmacist's role in chronic disease management, including monitoring the therapeutic effectiveness of medications and providing counseling to patients. We and the American Pharmaceutical Association believe that using pharmacists to provide such services may result in both direct and indirect cost savings to patients and third party payors, as well as provide economic incentives for pharmacists. We supplied L-D-X Systems to monitor patients in the Project.

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

Directed by the American Pharmaceutical Association Foundation and funded with an unrestricted educational grant from Merck and us, the Project involved 397 patients, 26 pharmacy practice sites in 12 states and over 60 pharmacists. It was designed to demonstrate how pharmacists who act as disease

9

12

managers for patients with high cholesterol or lipid disorders can improve persistence and compliance with therapy, working in collaboration with the patient's physician.

In March 2000, we announced the final results of the Project at the American Pharmaceutical Association's 147th Annual Meeting in Washington D.C. The Project's final results, based on 24 months of data, demonstrated that monitoring lipid levels at regular intervals and healthcare provider collaboration, increased rates for persistence to 93.6% and for compliance with medication therapy to 90.1%. The Project also found that 62.5% of these patients had reached and maintained the National Cholesterol Education Panel's cholesterol goals. These results represent a twofold to fourfold improvement when compared to historical findings. In addition, the March/April 2000 issue of the Journal of the American Pharmaceutical Association announced that our L-D-X System played an integral part in helping participating health care providers successfully manage patients with cholesterol disorders achieve optimal results.

SALES AND MARKETING

Our sales and marketing strategy is to capitalize on anticipated widespread community based testing to identify individuals who require treatment for high cholesterol and provide easy to use tools and information for therapeutic monitoring. In order to fulfill this strategy, we intend to expand our professional sales force and distribution capabilities, develop additional venues for convenient consumer testing and market interactive tools for personal health management directly to consumers, interested sponsors and partners.

Diagnostic Products

The sales and marketing strategy for our Diagnostic Products business is to increase penetration into the physician office laboratory and health promotion markets and leverage our installed base of L-D-X Analyzers through increased use of cassettes. We plan to dedicate a significant portion of the sales and marketing efforts of our Diagnostic Products business to educate current and potential owners of L-D-X Systems about the clinical and economic benefits of diagnostic screening and therapeutic monitoring with the L-D-X System and about new test cassettes as they become available for distribution. We also plan to continue to cultivate strategic relationships with development partners, pharmaceutical companies and distributors. We intend to leverage the technology, customer bases, marketing power and distribution networks of these partners to accelerate market penetration and cassette usage. Diagnostic Products' current marketing activities are primarily focused on:

- Physician Office Laboratories. We have entered into nonexclusive distribution agreements with two national medical products distributors, Physician Sales and Service and General Medical (currently a division of McKesson Corporation), which together have more than 1,300 sales professionals who focus on the physician office laboratory market. In addition, we have retained more than 30 regional distributors. We and our distributors focus our sales and marketing efforts on physicians whose practices include a high incidence of the cholesterol-related diseases targeted by our test cassettes, including cardiologists, lipid clinicians, internists and family practitioners.

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

- Health Promotion. We have ongoing relationships with 15 regional distributors who provide equipment and supplies to customers that conduct diagnostic screening for cholesterol and related lipid levels and diabetes. Additionally, through agreements with regional distributors and screening organizations, we provide the L-D-X System for the diagnostic screening of employees of Exxon Corporation, General Motors Corporation, Ford Motor Company and Sears, Roebuck and Co.
- International. Our international distribution strategy is to penetrate targeted geographic markets by selling directly to both high volume users and distributors in those markets. We have entered into non-exclusive agreements with 39 foreign distributors to distribute the L-D-X System, primarily in Europe, the Pacific Rim and Latin America.

10

13

WellCheck

The sales and marketing strategy for our WellCheck business is to broaden the geographic coverage of WellCheck's testing services and further penetrate the promotional, corporate wellness and other consumer testing venue markets. WellCheck's current marketing activities are primarily focused on:

- pharmaceutical companies;
- conventions;
- corporate wellness partners;
- retail venue partners; and
- public health programs.

COMPETITION

The diagnostic product markets in which we operate are intensely competitive. Our competition consists mainly of clinical and hospital laboratories, as well as manufacturers of bench top analyzers. The substantial majority of diagnostic tests used by physicians and other health care providers are currently performed by clinical and hospital laboratories. We expect that these laboratories will compete intensely to maintain dominance in the market. To achieve broad market acceptance, we must demonstrate that the L-D-X System is an attractive alternative to benchtop analyzers and clinical and hospital laboratories. This will require physicians to change their established means of having such tests performed. There can be no assurance that the L-D-X System will be able to compete with these other analyzers and testing services.

Companies with a significant presence in the diagnostic products market, such as Abbott Laboratories, Beckman Coulter, Inc. and Roche Diagnostics (a subsidiary of Roche Holdings Ltd.), have developed or are developing analyzers designed for preventive care testing. These competitors have substantially greater financial, technical, research and other resources and larger, more established marketing, sales, distribution and service organizations than us. Such competitors also offer broader product lines than us, have greater name recognition than us and offer discounts as a competitive tactic. In addition, several smaller companies are currently making or developing products that compete or will compete with ours. We believe we currently have a competitive advantage due to the status of the L-D-X System as the only CLIA waived system capable of performing multiple tests simultaneously on a single instrument. We expect that our competitors will compete actively to maintain and increase market share and will seek to develop multi-analyte tests that qualify for CLIA

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

waiver. There can be no assurance that our competitors will not succeed in obtaining CLIA waived status for their products or in developing or marketing technologies or products that are more effective and commercially attractive than our current or future products, or that would render our technology or products obsolete or noncompetitive.

Our WellCheck business is one of numerous preventive care testing services across the United States. Competing testing services companies are almost exclusively regional and privately held, with limited access to capital. While we believe the market opportunity for nationwide consumer testing of cholesterol vastly exceeds the current ability of all existing testing services combined, there is no guarantee that a larger, more well-known company with greater access to capital than us may not choose to take advantage of this market opportunity by competing with us.

Our current and future products must compete effectively with the existing and future products of our competitors primarily on the basis of ease of use, breadth of tests available, market presence, cost effectiveness, accuracy, immediacy of results and the ability to perform tests near the patient, to test multiple analytes from a single sample and to conduct tests without a skilled technician or pre-treating blood. There can be no assurance that we will have the financial resources, technical expertise or marketing, distribution or support capabilities to compete successfully in the future or, if we do have such resources and capabilities, that we will employ them successfully.

11

14

MANUFACTURING

We manufacture, test, perform quality assurance on, package and ship our products from our approximately 47,000 square foot facilities located in Hayward, California. We maintain control of those portions of the manufacturing process that we believe are complex and provide an important competitive advantage.

- L-D-X Analyzer. The L-D-X Analyzer incorporates a variety of subassemblies and components designed or specified by us, including an optical element, microprocessors, circuit boards, a liquid crystal display and other electrical components. These components and subassemblies are manufactured by a variety of third parties and are shipped to us for final assembly and quality assurance. Our manufacture of the L-D-X Analyzer consists primarily of assembly, testing, inspection and packaging. Testing consists of a burn-in period, functional tests and integrated system testing using specially produced test cassettes. We believe we can expand our current L-D-X Analyzer manufacturing capacity as needed.
- Cassettes. We purchase chemicals, membranes and other raw materials from third party suppliers and convert these raw materials, using proprietary processes, into single-use test cassettes. We believe our proprietary processes and custom designed equipment are important components of our cassette manufacturing operations. We have developed core manufacturing technologies, processes and production machinery, including membrane lamination and welding, discrete membrane impregnation, on-line calibration and software control of the manufacturing process. We have two fully operational cassette manufacturing lines. We are currently building a third manufacturing line, which is currently in preproduction validation stage and should be fully operational in July 2001.
- Raw Materials and Quality Assurance. Outside vendors provide us with the subassemblies, components and raw materials necessary for the manufacture

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

of our products. These subassemblies, components and raw materials are inspected and tested by our quality control personnel. Our quality control personnel also perform finished goods quality control and inspection and maintain documentation for compliance with quality systems regulations and other government manufacturing regulations. Our manufacturing facilities are subject to periodic inspection by regulatory authorities. Certain key components and raw materials used in the manufacturing of our products are currently provided by single source vendors and on a purchase order basis.

PATENTS AND PROPRIETARY TECHNOLOGY

We have nine United States patents covering various technologies, including the method for separating HDL from other lipoproteins in a dry chemistry format, the basic design of the testing cassette and the L-D-X Analyzer and the method of correcting for the effects of substances that can interfere with testing of a blood sample. We have also filed patent applications relating to our technology internationally under the Patent Cooperation Treaty and individual foreign applications. We are also the licensee of United States patents relating to the measurement of Lp(a), the measurement of bone resorption markers and our cassette technology.

Our current products incorporate technologies which are the subject of patents issued to, and patent applications filed by, others. We have obtained licenses for certain of these technologies and might be required to obtain licenses for others. There can be no assurance that we will be able to obtain licenses for technology patented by others on commercially reasonable terms, or at all, that we will be able to develop alternative approaches if we are unable to obtain licenses or that our current and future licenses will be adequate for the operation of our business. The failure to obtain such licenses or identify and implement alternative approaches could have a material adverse effect on our business, financial condition and results of operations.

We currently face patent infringement claims filed by Roche Diagnostics, a subsidiary of Roche Holdings Ltd., in several individual European countries. There can be no assurance that patent infringement claims will not be asserted by other parties in the future, that in such event we will prevail or that we will be able to obtain necessary licenses on reasonable terms, or at all. Adverse determinations in any litigation could subject us to significant liabilities and/or require us to seek licenses from third parties. If we are unable to obtain necessary licenses or are unable to develop or implement alternative technology, we may be unable to manufacture and

12

15

sell the affected products. Any of these outcomes could have a material adverse effect on our business, financial condition or results of operations.

We rely substantially on trade secrets, technical know-how and continuing invention to develop and maintain our competitive position. We work actively to foster continuing technological innovation to maintain and protect our competitive position, and we have taken security measures to protect our trade secrets and periodically explore ways to further enhance trade secret security. There can be no assurance that such measures will provide adequate protection for our trade secrets or other proprietary information. Although we have entered into proprietary information agreements with our employees, consultants and advisors, there can be no assurance that these agreements will provide adequate remedies for any breach.

GOVERNMENT REGULATION

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

Food and Drug Administration and Other Regulations

The manufacture and sale of our products are subject to regulation by numerous governmental authorities, principally the United States Food and Drug Administration (the "FDA") and corresponding state and foreign regulatory agencies. Pursuant to the Food, Drug and Cosmetics Act of 1938, as amended (the "FDC Act"), the FDA regulates the clinical testing, manufacture, labeling, distribution and promotion of medical devices. Noncompliance with applicable requirements can result in, among other things, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the government to grant pre-market clearance or pre-market approval for devices and criminal prosecution. The FDA also has the authority to request repair, replacement or refund of the cost of any device manufactured or distributed by us.

In the United States, medical devices are classified into one of three classes, Class I, II or III, on the basis of the controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I devices are subject to general controls (e.g., labeling, registration, listing and adherence to quality systems regulations). Class II devices are subject to general controls, pre-market notification and special controls (e.g., performance standards, post-market surveillance and patient registries). Generally, Class III devices are those that must receive pre-market approval from the FDA (e.g., life sustaining, life supporting and implantable devices, or new devices which have not been found substantially equivalent to legally marketed devices), and require clinical testing to assure safety and effectiveness.

Before a new device can be introduced into the market, the manufacturer must generally obtain marketing clearance through a pre-market notification under Section 510(k) of the FDC Act or a pre-market approval application under Section 515 of the FDC Act or be exempt from 510(k) requirements. Most Class I devices are exempt from 510(k) requirements. A 510(k) clearance typically will be granted if the submitted information establishes that the proposed device is "substantially equivalent" to a legally marketed Class I or II medical device or to a Class III medical device for which the FDA has not called for a pre-market approval. A 510(k) notification must contain information to support a claim of substantial equivalence, which may include laboratory test results or the results of clinical studies of the device in humans. It generally takes from four to twelve months from the date of submission to obtain 510(k) clearance, but it may take longer. A "not substantially equivalent" determination by the FDA, or a request for additional information, could delay the market introduction of new products that fall into this category. For any devices that are cleared through the 510(k) process, modifications or enhancements that could significantly affect safety or effectiveness or constitute a major change in the intended use of the device will require new 510(k) submissions. We obtained 510(k) clearance before marketing the L-D-X Analyzer and all existing test cassettes in the United States.

In general, we intend to develop and market tests that will require no more than 510(k) clearance. However, if we cannot establish that a proposed test cassette is substantially equivalent to a legally marketed device, we will be required to seek pre-market approval of the proposed test cassette from the FDA through the submission of a pre-market approval application. If a future product were to require submission of this type of application, regulatory approval of such product would involve a much longer and more costly process than a 510(k) clearance. We do not believe that our products under development will require the submission of a pre-market approval application, which can be lengthy, expensive and uncertain. A FDA review of a pre-

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

market approval application generally takes one to three years from the date it is accepted for filing, but may take significantly longer.

Any products manufactured or distributed by us pursuant to FDA clearance or approvals are subject to pervasive and continuing regulation by the FDA and certain state agencies, including record keeping requirements and reporting of adverse experience with the use of the device. Labeling and promotional activities are subject to scrutiny by the FDA and, in certain circumstances, by the Federal Trade Commission. Current FDA enforcement policy prohibits the marketing of approved medical devices for unapproved uses.

The FDC Act regulates our quality control and manufacturing procedures by requiring us and our contract manufacturers to demonstrate compliance with quality systems regulations. The FDA monitors compliance with these requirements by requiring manufacturers to register with the FDA, which subjects them to periodic inspections. The State of California also regulates and inspects our manufacturing facilities. We have been inspected twice by the State of California to date and are manufacturing under an issued medical device manufacturer's facility license from the State of California. If any violations of our applicable regulations are noted during a FDA, European Notified Body or State of California inspection of our manufacturing facilities or those of our contract manufacturers, the continued marketing of our products could be materially adversely affected.

The European Union ("EU") has promulgated rules that require that devices such as ours receive the right to affix the CE mark, a symbol of adherence to applicable EU directives. We have completed all the testing necessary to comply with applicable regulations to currently be eligible for self certification and currently have the right to affix the CE mark to our products. While we intend to satisfy the requisite policies and procedures that will permit us to continue to affix the CE mark to our products in the future, there can be no assurance that we will be successful in meeting EU certification requirements. Failure to receive the right to affix the CE mark may prohibit us from selling our products in EU member countries and could have a material adverse effect on our business, financial condition and results of operations.

We and our products are also subject to a variety of state and local laws and regulations in those states or localities where our products are or will be marketed. Any applicable state or local laws or regulations may hinder our ability to market our products in those states or localities. For example, eight states have regulations that impose requirements on pharmacies and/or pharmacists that perform clinical testing, four of which have regulations that prohibit certain pharmacy-based testing. We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. There can be no assurance that we will not be required to incur significant costs to comply with such laws and regulations now or in the future or that such laws or regulations will not have a material adverse effect on us.

Changes in existing requirements or adoption of new requirements or policies could increase the cost of or otherwise adversely affect our ability to comply with regulatory requirements. Failure to comply with regulatory requirements could have a material adverse effect on us.

Clinical Laboratory Improvement Act Regulations

The use of our products in the United States is subject to CLIA, which provides for federal regulation of laboratory testing, an activity also regulated by most states. Laboratories must obtain either a registration certificate from the Health Care Finance Administration, register with an

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

approved accreditation agency or obtain a state license in a state with a federally approved license program. The CLIA regulations seek to ensure the quality of medical testing. The three primary mechanisms to accomplish this goal are daily quality control requirements to ensure the accuracy of laboratory devices and procedures, proficiency testing to measure testing accuracy and personnel standards to assure appropriate training and experience for laboratory workers. CLIA categorizes tests as "waived," or as being "moderately complex" or "highly complex" on the basis of specific criteria. To successfully commercialize tests that are currently under development, we believe it will be critical to obtain waived classification for such tests under CLIA, because CLIA waiver allows health care providers to use the L-D-X System at a lower cost.

14

17

THIRD PARTY REIMBURSEMENT

In the United States, health care providers, such as hospitals and physicians, that purchase products such as the L-D-X System and single-use test cassettes 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. Our ability to commercialize our products successfully in the United States will depend in part on the extent to which reimbursement for the costs of tests performed with the L-D-X System and related treatment will be available from government health authorities, private health insurers and other third party payors. Third party payors can affect the pricing or the relative attractiveness of our products by regulating the maximum amount of reimbursement provided by such payors for testing services. Reimbursement is currently not available for certain uses of our products in particular circumstances. For example, tests performed in the health promotion market are generally not subject to reimbursement. Pharmacists also face blocking state legislation in a number of states, which precludes them from accessing federally available reimbursement codes and practices. Third party payors are increasingly scrutinizing and challenging the prices charged for medical products and services. Decreases in reimbursement amounts for tests performed using our products may decrease amounts physicians and other practitioners are able to charge patients, which in turn may adversely affect our ability to sell our products on a profitable basis. In addition, certain health care providers are moving toward a managed care system in which such providers contract to provide comprehensive health care for a fixed cost per patient. Managed care providers are attempting to control the cost of health care by authorizing fewer elective procedures, such as the screening of blood for chronic diseases. We are unable to predict what changes will be made in the reimbursement methods used by third party payors. The inability of healthcare providers to obtain reimbursement from third party payors, or changes in third party payors' policies toward reimbursement of tests using our products, could have a material adverse effect on our business, financial condition and results of operations. Given the efforts to control and reduce health care costs in the United States in recent years, there can be no assurance that currently available levels of reimbursement will continue to be available in the future for our existing products or products under development.

In 1991, the Health Care Finance Administration ("HCFA") adopted regulations providing for the inclusion of capital related costs in the prospective payment system for hospital inpatient services under which most hospitals are reimbursed by Medicare on a per diagnosis basis at fixed rates unrelated to actual costs, based on diagnostic related groups. Under this system of reimbursement, equipment costs generally are not reimbursed separately, but rather are included in a single, fixed rate, per patient reimbursement. Medicare reform legislation requires HCFA to implement a prospective payment system for outpatient hospital services as well. This system may also provide for a

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

per-patient fixed rate reimbursement for outpatient department capital costs. We believe these regulations place more pressure on hospitals' operating margins, causing them to limit capital expenditures. These regulations could have an adverse effect on us if hospitals decide to defer obtaining medical equipment as a result of any such limitation on their capital expenditures. The Medicare legislation also requires HCFA to adopt uniform coverage and administration policies for laboratory tests. We are unable to predict what adverse impact on us, if any, additional government regulations, legislation or initiatives or changes by other payors affecting reimbursement or other matters that may influence decisions to obtain medical equipment may have.

We believe the escalating cost of medical products and services has led to and will continue to lead to increased pressures on the health care industry, both foreign and domestic, to reduce the cost of products and services, including products offered by us. In addition, market acceptance of our products in international markets is dependent, in part, on the availability of reimbursement within prevailing health care payment systems. Reimbursement and health care payment systems in international markets vary significantly by country, and include both government sponsored health care and private insurance. There can be no assurance in either domestic or foreign markets that third party reimbursement and coverage will be available or adequate, that current reimbursement amounts will not be decreased in the future or that future legislation, regulation or reimbursement policies of third party payors will not otherwise adversely affect the demand for our products or our ability to sell our products on a profitable basis.

15

18

PRODUCT LIABILITY AND INSURANCE

The sale of our products entails risk of product liability claims. The medical testing industry has historically been litigious, and we face financial exposure to product liability claims if use of our products results in personal injury. We also face the possibility that defects in the design or manufacture of our products might necessitate a product recall. There can be no assurance that we will not experience losses due to product liability claims or recalls in the future. We currently maintain product liability insurance, but there can be no assurance that the coverage limits of our insurance policies will be adequate. Such insurance is expensive, difficult to obtain and no assurance can be given that product liability insurance can be maintained in the future on acceptable terms, or in sufficient amounts to protect us against losses due to liability, or at all. An inability to maintain insurance at an acceptable cost or to otherwise protect against potential product liability could prevent or inhibit the continued commercialization of our products. In addition, a product liability claim in excess of relevant insurance coverage or a product recall could have a material adverse effect on our business, financial condition and results of operations.

The services performed by our WellCheck business entail risk of professional liability and cyber liability claims. The medical testing industry has historically been litigious, and we face financial exposure to professional liability, malpractice and cyber liability claims if services provided by our employees and our products result in personal injury. There can be no assurance that we will not experience losses due to such claims in the future. We currently maintain professional liability and cyber liability insurance, but there can be no assurance that the coverage limits of our insurance policies will be adequate. Such insurance is expensive, difficult to obtain and no assurance can be given that such insurance can be maintained in the future on acceptable terms, or in sufficient amounts to protect us against losses due to liability, or at all. An inability to maintain insurance at an acceptable cost or to otherwise protect against potential claims could prevent or inhibit the

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

continued commercialization of our products and services. In addition, a claim in excess of relevant insurance coverage could have a material adverse effect on our business, financial condition and results of operations.

We have liability insurance covering our property and operations with coverage, deductible amounts and exclusions, which we believe are customary for companies of our size in our industry. However, there can be no assurance that our current insurance coverage is adequate or that we will be able to maintain insurance at an acceptable cost or otherwise to protect against liability.

EMPLOYEES

As of March 30, 2001, we employed 221 full-time, regular associates, including 136 in our Diagnostic Products business, 61 in our WellCheck business, eight in our WellCheck.com business and 16 in corporate administration. There were 78 associates in sales, marketing and administration, 84 associates in manufacturing, 43 associates in field testing and 16 associates devoted to research and development. None of the associates is covered by a collective bargaining agreement, and management considers relations with employees to be excellent.

16

19

EXECUTIVE OFFICERS

The names, ages and positions of our current executive officers are as follows:

| NAME | AGE | POSITION |
|----------------------------|-----|--|
| ---- | --- | ----- |
| Warren E. Pinckert II..... | 57 | President, Chief Executive Officer and Director |
| William W. Burke..... | 42 | Vice President of Finance, Chief Financial Officer, Treasurer and Secretary |
| Robert J. Dominici..... | 57 | Executive Vice President and Chief Operating Officer (Diagnostic Products) |
| David A. Gyorke..... | 41 | Vice President of Operations (Diagnostic Products) |
| Timothy I. Still..... | 35 | Vice President of Sales and Marketing (Diagnostic Products) |
| Kevin R. Stromberg..... | 39 | Vice President of Engineering (WellCheck) |
| Terry L. Wassmann..... | 54 | Vice President of Human Resources |
| Thomas E. Worthy..... | 59 | Vice President of Development and Regulatory Affairs (Diagnostic Products) |

Warren E. Pinckert II has served as our President, Chief Executive Officer and a Director since June 1993. Mr. Pinckert served as Executive Vice President of Operations of Cholestech from 1991 to June 1993, and as Chief Financial Officer and Vice President of Business Development of Cholestech from 1989 to June 1993. Mr. Pinckert also served as Secretary of Cholestech from 1989 to January 1997. Before joining Cholestech, Mr. Pinckert was Chief Financial Officer of Sunrise Medical Inc., an international durable medical products manufacturer, from 1983 to 1989. Mr. Pinckert also serves on the board of directors of PacifiCare Health Systems, Inc., a managed care organization. Mr. Pinckert holds a Bachelor of Science degree in Accounting and a Masters of Business Administration degree from the University of Southern California and is a certified public accountant.

William W. Burke has served as Vice President of Finance, Chief Financial

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

Officer, Treasurer and Secretary since joining our company in April 2001. From August 1998 to March 2001, Mr. Burke was a Managing Director in Bear, Stearns & Co. Inc.'s investment banking department where he was responsible for broadening Bear Stearns' investment banking franchise in the southwest in several industries, including healthcare. As a Managing Director in Everen Securities, Inc.'s ("Everen's") investment banking group from May 1991 to May 1995 and January 1998 to August 1998, he specialized in advising emerging growth medical technology companies. From May 1995 to January 1998, he served as Managing Director and Director of Healthcare Investment Banking for Principal Financial Securities, Inc., which was acquired by Everen in January 1998. Mr. Burke holds a Bachelor of Business Administration degree in Finance from the University of Texas at Austin and a Masters of Business Administration degree from the University of Pennsylvania's Wharton Graduate Business School.

Robert J. Dominici joined our company as Executive Vice President of Marketing and Sales in August 1998. In September 1999, Mr. Dominici was promoted to Chief Operating Officer of our Diagnostic Products business. From January 1997 to May 1998, Mr. Dominici served as Senior Vice President/General Manager Corporate Accounts for Boehringer Mannheim Corporation, a healthcare diagnostic products company. Before his position as Senior Vice President, Corporate Accounts, Mr. Dominici held other positions within Boehringer Mannheim including Vice President Marketing, Sales and Services and President of the Laboratory Systems Division. From February 1992 to December 1996, he was President and Chief Executive Officer of Microgenics Corporation, a wholly owned subsidiary of Boehringer Mannheim. Mr. Dominici holds a Bachelor of Science degree in Biology and Chemistry from Otterbein College.

David A. Gyorke was recently promoted to the position of Vice President of Operations for our Diagnostic Products business in July 2000. Mr. Gyorke previously served as our Director of the Operations' Engineering Groups. Before joining Cholestech in January 1999, Mr. Gyorke was the Manufacturing & Technology Engineering Manager of Target Therapeutics, a neuro medical device manufacturer and a division of the Boston Scientific Corporation. During his tenure with Target, Mr. Gyorke was responsible for various product lines plus implementing new processing technologies for the neuro catheter, balloon, guidewire and embolic

17

20

coil production lines. Mr. Gyorke's experience also includes positions with Bio-Rad Laboratories, Diasonics Ultrasound Inc. and defense contractors ArgoSystems, Inc. and Raytheon Company. His engineering internship was with McDonnell Douglas. Mr. Gyorke holds a Bachelor of Science degree in Industrial Engineering from the California Polytechnic State University, San Luis Obispo.

Timothy I. Still is Vice President of Sales and Marketing and Sales for our Diagnostic Products business. Mr. Still joined Cholestech as the Senior Director of Marketing in December 1997. Before joining Cholestech, Mr. Still was a Director of Global Marketing and Business Development for Boehringer Mannheim Corporation. During his tenure with Boehringer Mannheim from August 1992 to November 1997, Mr. Still was responsible for the global sales and marketing of the CEDIA immunoassay product line. Before joining Boehringer Mannheim, Mr. Still was a Product Manager with Bio-Rad Laboratories from June 1992 to August 1992 where he was responsible for the marketing of various immunoassay reagents and instrumentation. Mr. Still holds a Bachelor of Science degree in Biological Sciences from the University of California at Davis and a Masters of Business Administration degree in Marketing and Entrepreneurship from the University of Southern California.

Kevin R. Stromberg is Vice President of Engineering and Operations for our WellCheck business. Mr. Stromberg was previously Vice President of Engineering

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

of WellCheck.com from April 2000 to January 2001. Before joining Cholestech, he was Director of Information technology for Bay Alarm Company from February 1998 to April 2000. Before Bay Alarm, Mr. Stromberg held the position of Engineering Manager from January 1996 to February 1998 for Sun Microsystems, Inc. From 1994 to 1996, he held several positions at Shared Medical Systems' Allegra Division. Additionally, he held positions from 1992 to 1994 with Interactive Development Environments, Inc. and Wollongong Software companies and operated his own consulting business. Mr. Stromberg holds a Bachelor of Science degree in Computer Information Systems from the University of San Francisco.

Terry L. Wassmann joined our company in March 2000 as Vice President of Human Resources. Before joining Cholestech, Ms. Wassmann served as Staff Relations Manager with Robert Half International from July 1999 to March 2000. From February 1986 until December 1999, Ms. Wassmann was employed by Boehringer Mannheim where She held numerous positions within the Human Resources department, including the Director of Human Resources of the Indiana and California based Diagnostics Division.

Dr. Thomas E. Worthy is Vice President, Development and Regulatory Affairs for our Diagnostic Products business. He was previously our Director of Technical Affairs. Before joining Cholestech, Dr. Worthy held Director of Research and Development positions at Microgenics Corporation from February 1988 to April 1998, a division of Boehringer Mannheim Corporation, and at MetPath, Inc. from May 1981 to February 1988. He holds a Doctor of Philosophy degree in Radiation Biology from the University of Tennessee, a Master of Science degree in Microbiology from Northern Illinois University and a Bachelor of Arts degree in Biology from Albion College.

ITEM 2. PROPERTIES

We lease 47,000 square feet in Hayward, California and 5,100 square feet in Oakland, California. Our facilities contain approximately 8,000 square feet of laboratory space and 10,000 square feet of manufacturing space with the balance devoted to marketing and administrative and common areas. Our original lease on the main Hayward facility expired on March 31, 2000 and we have agreed to renew the lease for two years at 90% of the then current market rate. We believe this facility is adequate to meet our requirements through the expiration of our lease. Additionally, we are in negotiations to extend the lease for four to eight years for our current headquarters location and anticipate finalizing this lease in mid 2001. We also rent 3,000 square feet on a month-to-month basis in Hammond, Louisiana.

ITEM 3. LEGAL PROCEEDINGS

On February 5, 1999, a complaint entitled *Ree v. Pinckert, et al.*, No. C99-0562 (PJH) was filed in the United States District Court for the Northern District of California. The action is a putative class action and the complaint alleges that our company and certain of its current and former officers violated the federal

securities laws by making false and misleading statements concerning our company and its business during the period of June 28, 1996 through June 25, 1998. On June 14, 2001, we executed an agreement in principle with plaintiffs to resolve this matter for a payment \$3 million by our insurance carrier. We recorded a \$1.3 million charge during the year ended March 30, 2001 for legal fees and insurance costs related to resolving this matter. The settlement is contingent on Court approval.

On December 23, 1999, a complaint requesting an injunction, No. ES-580-199,

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

was filed in Zug, Switzerland by Roche Diagnostics seeking a cease and desist order barring us and two of our distributors from distributing HDL assay single-use test cassettes in Switzerland. The complaint alleges that we violated a Roche European patent for HDL. We have filed our response to the complaint. On July 11, 2000 the court denied the plaintiff's request for an injunction and ordered them to pay a portion of our legal fees. The plaintiff has appealed the court ruling. At this point in time no schedule has been set regarding additional court activity. There can be no assurance as to whether the plaintiffs will take any additional action, or any additional action be resolved in our favor.

In September 2000, we were served a complaint, No. Ei/Ti ROCH 04002, filed in Vienna, Austria by Roche Diagnostics, a subsidiary of Roche Holdings, Ltd., seeking a cease and desist order barring us and one of our distributors from distributing HDL assay single-use test cassettes in Austria. The complaint alleges that we violated a Roche European patent for HDL. At this point, no schedule has been set regarding court activity. There can be no assurance as to whether the plaintiffs will take any additional action or whether any additional action will be resolved in our favor.

Additionally, in January 2000, a complaint, No. 4 O 4/00, was filed in the District Court, Dusseldorf, Germany by Roche Diagnostics against us and two of our distributors seeking a cease and desist order barring the distributors from shipping HDL single-use test cassettes into Germany. The complaint alleges we and our distributors violated a Roche German priority patent for HDL by selling our single-use test cassette containing a HDL assay. The court has requested additional information be submitted by both parties, but has not made any ruling or set additional court dates. We believe the suit is without merit and intend to defend the case vigorously. Therefore, we do not believe that the outcome of this matter will result in a material adverse effect. However, there can be no assurance that the lawsuit will be resolved in our favor.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None.

19

22

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock is quoted on the NASDAQ National Market under the symbol "CTEC." On March 30, 2001, the last reported sale price for our common stock on the NASDAQ National Market was \$4.81 per share. The following table sets forth the quarterly high and low trading prices for our common stock.

| | HIGH | LOW |
|---------------------|---------|--------|
| | ----- | ----- |
| FISCAL YEAR 2000 | | |
| First Quarter..... | \$ 2.97 | \$1.94 |
| Second Quarter..... | 8.38 | 2.25 |
| Third Quarter..... | 7.50 | 5.63 |
| Fourth Quarter..... | 10.44 | 5.19 |
| FISCAL YEAR 2001 | | |
| First Quarter..... | \$ 8.97 | \$6.00 |
| Second Quarter..... | 8.00 | 6.38 |

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

| | | |
|---------------------|------|------|
| Third Quarter..... | 7.50 | 4.81 |
| Fourth Quarter..... | 6.59 | 3.69 |

As of March 30, 2001 there were approximately 211 holders of record of our common stock.

We have never paid cash dividends on our common stock and do not anticipate paying cash dividends in the foreseeable future.

20

23

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated financial data should be read in conjunction with our consolidated financial statements and notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations". The following selected consolidated statement of operations data for the fiscal years ended March 30, 2001, March 31, 2000 and March 26, 1999 and the selected consolidated balance sheet data as of March 30, 2001 and March 31, 2000 are derived from, and qualified by reference to, the audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. The selected consolidated statement of operations data for the fiscal years ended March 27, 1998 and March 28, 1997 and the consolidated balance sheet data as of March 26, 1999, March 27, 1998 and March 28, 1997 have been derived from our audited consolidated financial statements not included herein. These historical results are not necessarily indicative of the results of operations to be expected from any future period.

| | YEAR ENDED MARCH 31, (1) | | | | |
|---|---------------------------------------|----------|----------|----------|---------|
| | 2001 | 2000 | 1999 | 1998 | 1997 |
| | (IN THOUSANDS, EXCEPT PER SHARE DATA) | | | | |
| CONSOLIDATED STATEMENT OF OPERATIONS DATA: | | | | | |
| Revenue (2)..... | \$37,003 | \$27,549 | \$22,032 | \$21,664 | \$12,86 |
| Cost of revenue(2)..... | 15,280 | 11,211 | 10,252 | 10,513 | 6,95 |
| | ----- | ----- | ----- | ----- | ----- |
| Gross profit..... | 21,723 | 16,338 | 11,780 | 11,151 | 5,90 |
| | ----- | ----- | ----- | ----- | ----- |
| Operating expenses: | | | | | |
| Sales and marketing..... | 11,388 | 7,032 | 6,606 | 5,380 | 4,10 |
| Research and development..... | 2,586 | 3,021 | 2,703 | 2,224 | 1,34 |
| Website and other related costs..... | 1,952 | -- | -- | -- | - |
| General and administrative..... | 5,079 | 3,510 | 2,381 | 2,087 | 1,53 |
| Goodwill amortization..... | 709 | 100 | -- | -- | - |
| Legal and other related..... | 1,312 | 219 | 826 | -- | - |
| Impairment charge..... | 1,958 | -- | -- | -- | - |
| | ----- | ----- | ----- | ----- | ----- |
| Total operating expenses..... | 24,984 | 13,882 | 12,516 | 9,691 | 6,98 |
| | ----- | ----- | ----- | ----- | ----- |
| Income (loss) from operations..... | (3,261) | 2,456 | (736) | 1,460 | (1,08 |
| Interest and other income, net..... | 655 | 805 | 663 | 569 | 27 |
| | ----- | ----- | ----- | ----- | ----- |
| Income (loss) before taxes..... | (2,606) | 3,261 | (73) | 2,029 | (80 |
| Provision for income taxes..... | -- | 129 | -- | 41 | - |
| | ----- | ----- | ----- | ----- | ----- |
| Net income (loss)..... | \$(2,606) | \$ 3,132 | \$ (73) | \$ 1,988 | \$ (80 |

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

| | ===== | ===== | ===== | ===== | ===== |
|--|----------|---------|-----------|---------|----------|
| Net income (loss) per share: | | | | | |
| Basic..... | \$ (.22) | \$ 0.27 | \$ (0.01) | \$ 0.18 | \$ (0.0) |
| | ===== | ===== | ===== | ===== | ===== |
| Diluted..... | \$ (.22) | \$ 0.26 | \$ (0.01) | \$ 0.17 | \$ (0.0) |
| | ===== | ===== | ===== | ===== | ===== |
| Shares used to compute net income (loss) per share:(3) | | | | | |
| Basic..... | 12,046 | 11,724 | 11,484 | 11,289 | 10,38 |
| | ===== | ===== | ===== | ===== | ===== |
| Diluted..... | 12,046 | 11,920 | 11,484 | 11,905 | 10,38 |
| | ===== | ===== | ===== | ===== | ===== |

MARCH 31, (1)

| | ----- | ----- | ----- | ----- | ----- |
|--|-------|-------|-------|-------|-------|
| | 2001 | 2000 | 1999 | 1998 | 1997 |
| | ----- | ----- | ----- | ----- | ----- |

(IN THOUSANDS)

CONSOLIDATED BALANCE SHEET DATA:

| | | | | | |
|---|-----------|-----------|-----------|-----------|----------|
| Cash, cash equivalents and marketable securities..... | \$ 12,365 | \$ 13,741 | \$ 11,427 | \$ 14,751 | \$ 14,00 |
| Working capital..... | 10,254 | 11,522 | 13,342 | 17,662 | 16,12 |
| Total assets..... | 30,742 | 32,218 | 24,283 | 25,788 | 21,08 |
| Accumulated deficit..... | (48,030) | (45,424) | (48,556) | (48,483) | (50,47 |
| Shareholders' equity..... | 24,858 | 26,476 | 21,769 | 21,446 | 18,70 |

21

24

-
- (1) Our fiscal year is a 52-53 week period ending on the last Friday in March. All fiscal years referenced in this Annual Report on Form 10-K consisted of 52 weeks, except fiscal 2000, which consisted of 53 weeks. For convenience, we have indicated in this Annual Report on Form 10-K that our fiscal year ends on March 31 and refer to the fiscal year ending March 30, 2001 as fiscal 2001, the fiscal year ending March 31, 2000 as fiscal 2000, the fiscal year ending March 26, 1999 as fiscal 1999, the fiscal year ending March 27, 1998 as fiscal 1998 and the fiscal year ending March 28, 1997 as fiscal 1997.
 - (2) Revenue and costs of revenue figures have been revised as a result of the retroactive adoption of EITF 00-10 "Accounting for Shipping and Handling Fees and Costs".
 - (3) See Note 1 of Notes to Consolidated Financial Statements for an explanation of the shares used to compute net income (loss) per share.

22

25

ITEM 7: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Certain statements in this "Management's Discussion and Analysis of Financial Condition and Results of Operations" are forward looking statements. These statements relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

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

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

OVERVIEW

In the past fiscal year, we engaged in three business segments:

- Diagnostic Products -- which develops, manufactures and markets our L-D-X(R) System (the "L-D-X System") which performs near-patient diagnostic tests that assist in assessing the risk of certain cholesterol-related diseases, certain liver diseases, and in the monitoring of therapy to treat that diseases.
- WellCheck -- which conducts consumer testing within the United States that assesses the risk of certain cholesterol-related and other diseases and assists in the monitoring of therapy to treat those diseases.
- WellCheck.com -- which provides interactive tools to consumers through the Internet to better assess the risk of certain cholesterol-related and other diseases and to monitor and motivate personal health management of those diseases.

Diagnostic Products currently manufactures and markets the L-D-X System, including the L-D-X Analyzer and a variety of single-use test cassettes, in the United States and internationally. The L-D-X System allows health care providers to perform individual tests or combinations of tests with a single drop of blood from a fingerstick within five minutes. Our current products measure and monitor blood cholesterol, related lipids, glucose and liver function, and are used to test patients at risk of or suffering from heart disease, diabetes or liver disease.

WellCheck currently provides cholesterol and related testing services and education to the general public using the L-D-X System and creates opportunities for sales of test cassettes manufactured by our Diagnostic Products business. WellCheck's professionals provide high quality services and offer test event expertise to both event sponsors and consumers. As part of our testing services, we utilize our proprietary TEAMS technology which automates registration, data acquisition and information management at promotional, corporate wellness and other consumer testing events and provides consumers with a personalized risk assessment for heart disease. Substantially all of WellCheck's revenue is derived from promotional programs with major pharmaceutical companies marketing lipid-lowering statin drugs. We believe an opportunity exists to further expand our testing services business in the promotional, corporate wellness, retail

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

markets and other convenient venues which broaden consumer access to testing while assisting consumer product companies, such as pharmaceutical companies, in customer acquisition. Our goal is to develop the first nationwide consumer testing services company for chronic diseases.

23

26

We launched WellCheck.com operations in October 1999 to develop website content and TEAMS technology to provide consumers with interactive tools to learn about and manage cholesterol-related diseases. Based on our determination that adequate sponsor funding for a retail-oriented, chronic disease management model roll out was unavailable at present, we refocused on expanding our activities in the promotional and corporate wellness market. As a result, our WellCheck.com business unit and its consumer-oriented website have been repositioned as a technology support tool for our WellCheck business. In the fourth quarter of fiscal 2001, we recorded a non-cash, non-recurring charge of \$1.96 million to reflect the impairment of certain intangible assets associated with the development of WellCheck.com's website and database.

More recently we merged WellCheck.com into WellCheck. We intend to operate and manage WellCheck and WellCheck.com as one business segment in fiscal 2002 and beyond.

RESULTS OF OPERATIONS

YEARS ENDED MARCH 30, 2001 AND MARCH 31, 2000

Revenue. Our total revenue increased 34.3% to \$37.0 million in fiscal 2001 from \$27.5 million in fiscal 2000. Diagnostic Products represented 87.8% of total revenue in fiscal 2001 and 98.0% of total revenue in fiscal 2000.

International revenue represented 17.4% of our total revenue in fiscal 2001, compared to 17.6% in fiscal 2000. In fiscal 2001 all international revenue related to the Diagnostic Products business unit.

Segment performance was as follows:

- Diagnostic Products revenue increased 20.3% to \$32.5 million in fiscal 2001 from \$27.0 million in fiscal 2000. The increase in revenue mainly reflected an 18.1% increase in unit sales of single-use test cassettes. The growth was in the physician office laboratory, health promotion and international markets. Additionally, unit sales of the L-D-X System increased by 42.9%. L-D-X sales increased in all markets, other than pharmacy.
- WellCheck revenue increased 706.7% to \$4.4 million in fiscal 2001 from \$549,000 in fiscal 2000. The increase in revenue reflected the fact that WellCheck was only included in our results of operations during the last two months of fiscal 2000.
- WellCheck.com revenue increased to \$85,000 in fiscal 2001 from no revenue in fiscal 2000.

Cost of Revenue. Our cost of revenue increased 36.3% to \$15.3 million in fiscal 2001 from \$11.2 million in fiscal 2000. Gross margins were 58.7% in fiscal 2001 and 59.3% in fiscal 2000. Diagnostic Products accounted for 92.0% of our cost of products sold and the other 8% related to service revenue from WellCheck and WellCheck.com in fiscal 2001. Diagnostic Products accounted for 98.6% of our costs of products sold and 1.4% related to service revenue in fiscal 2000.

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

Segment performance was as follows:

- Diagnostic Products cost of revenue includes direct labor, direct material, overhead and royalties. Cost of revenue increased 27.1% to \$14.1 million in fiscal 2001 from \$11.1 million in fiscal 2000. The increase was primarily related to the higher unit sales of single-use test cassettes, and costs of validations and testing of our new manufacturing line for cassettes which is currently in preproduction validation. Gross margin was 56.7% in fiscal 2001 and 59.1% in fiscal 2000. The gross margin decline was primarily attributable to spending related to prepare the new production equipment for full operation during July 2001.

We have licensed certain technology used in the manufacturing of certain of our products. A related agreement, which expires in 2006, requires us to pay a royalty of 2.0% on net sales of single use test cassettes. Total royalty expense was \$490,000 in fiscal 2001 and \$456,000 in fiscal 2000 and such amounts were charged to cost of product revenue.

24

27

- WellCheck cost of revenue includes reimbursed travel expenses, laboratory services, medical waste disposal and the cost of medical testing equipment and supplies. Costs of product provided by the Diagnostic Products business are eliminated on consolidation. Total cost of revenue was \$1.2 million in fiscal 2001 and \$155,000 for the two months of operations in fiscal 2000.
- WellCheck.com does not have any costs associated with its revenue. Costs associated with the maintenance of TEAMS and the website are included in website and related costs in the consolidated statement of operations.

Operating Expenses

Sales and Marketing. Our sales and marketing expense includes salaries, commissions, bonuses, expenses for outside services related to marketing programs and travel expenses. Sales and marketing expenses increased 61.9% to \$11.4 million in fiscal 2001 from \$7.0 million in fiscal 2000. Sales and marketing expenses increased to 30.8% of revenue in fiscal 2001 from 25.5% in fiscal 2000. Diagnostic Products accounted for 70% of sales and marketing expenses for fiscal 2001 and 97.2% of sales and marketing expenses for fiscal 2000.

Sales and marketing expense in each of our segments was as follows:

- Diagnostic Products sales and marketing expense increased 16.6% to \$8.0 million in fiscal 2001 from \$6.8 million in fiscal 2000. The increase relates to increased advertising, trade show and promotional costs. Sales and marketing expense decreased to 24.5% of revenue in fiscal 2001 from 25.3% of revenue in fiscal 2000.
- WellCheck sales and marketing expense increased significantly to \$2.7 million in fiscal 2001 from \$200,000 in fiscal 2000. This increase reflects the fact that WellCheck was only included in our results of operations for last two months of fiscal 2000.
- WellCheck.com sales and marketing expense was \$683,000 in fiscal 2001. During fiscal 2000 there was no sales and marketing expense as this business was focused on developing the concept and structure of the website and had not started contacting potential customers for sponsorship or advertising related to the business.

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

Research and Development. Our research and development expense includes salaries, bonuses, and expenses for outside services, supplies and amortization of capital equipment. Research and development expense decreased 14.4% to \$2.6 million in fiscal 2001 from \$3.0 million in fiscal 2000. Research and development expenses as a percentage of revenue decreased to 7.0% in fiscal 2001 compared to 11.0% in fiscal 2000. Diagnostic Products accounted for 84.9% of research and development expense in fiscal 2001 and 79.8% of research and development expense in fiscal 2000. WellCheck.com incurred 15.1% of the research and development expense reported in fiscal 2001.

Research and development expense in each of our segments was as follows:

- Diagnostic Products research and development expense decreased 9.0% to \$2.2 million in fiscal 2001 from \$2.4 million in fiscal 2000. This reduction was mainly attributable to reduced head count and related expenses as the ALT single-use test cassette approached development completion. Research and development expense as a percentage of revenue decreased to 6.8% in fiscal 2001 compared to 8.9% in fiscal 2000.
- WellCheck incurred no research and development expense in fiscal 2001.
- WellCheck.com research and development expense was \$392,000 in fiscal 2001, net of \$874,000 of certain capitalized website costs and \$286,000 of capitalized TEAMS software development costs.

General and Administrative. Our general and administrative expense includes salaries and benefits, as well as expenses for outside professional services including information services, legal fees, accounting, our medical advisory board and costs associated with our board of directors. General and administrative expense increased by 44.7% to \$5.1 million in fiscal 2001 from \$3.5 million in fiscal 2000. General and administrative expense increased to 13.7% of revenue in fiscal 2001 from 12.7% in fiscal 2000. Diagnostic Products

25

28

represented 52.1% of general and administrative expense in fiscal 2001 and 67.5% of general and administrative expenses in fiscal 2000. WellCheck.com accounted for 25.4% and WellCheck accounted for 22.5% of the general and administrative expense in fiscal 2001.

General and administrative expense in each of our segments was as follows:

- Diagnostic Products general and administrative expense increased by 11.5% or \$272,000 to \$2.6 million in fiscal 2001 from \$2.4 million in fiscal 2000. General and administrative expense decreased to 8.1% of revenue in fiscal 2001, compared to 8.8% in fiscal 2000. The increase relates to the wages, benefits and other costs for the segment's Chief Operating Officer and staff. This position was not created until the third quarter of fiscal 2000.
- WellCheck general and administrative expense was \$1.1 million in fiscal 2001 compared to \$245,000 in fiscal 2000. In fiscal 2001 general and administrative expense was 25.8% of revenue. The increase reflects that WellCheck was only included in our results of operations for the last two months of fiscal 2000.
- WellCheck.com general and administrative expense was \$1.3 million in fiscal 2001 compared to \$896,000 in fiscal 2000. The increase was due to WellCheck.com being included in our results of operations for the last six months of fiscal 2000.

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

Goodwill Amortization. Goodwill amortization expense includes the amortization of capitalized costs associated with the purchase of Health Net in January 2000. Amortization expense increased 609.0% to \$709,000 in fiscal 2001 from \$100,000 in fiscal 2000. All costs were associated with the WellCheck business.

Legal and Other Related. Our legal and related expense includes professional consulting fees, court related costs, and other fees relating to litigation. Legal and related expense increased 499% to \$1.3 million in fiscal 2001 from \$219,000 in fiscal 2000. All costs incurred in fiscal 2001 and fiscal 2000 relate to the same class action lawsuit for which a settlement was reached in June 2001.

Impairment Charge. In the fourth quarter of fiscal 2001 we recorded impairment expense of \$1.96 million relating to certain capitalized website and database development costs. As we have been unable to generate significant revenues from our website and related database, the determination was that the carrying value of these costs exceeded their estimated future cash flows. There was no impairment expense during fiscal 2000.

Interest and Other Income, Net. Interest income reflects income from the investment of cash balances and marketable securities, net of expenses. Interest income decreased 18.6% to \$655,000 in fiscal 2001 from \$805,000 in fiscal 2000. This decrease was primarily the result of reduced cash equivalents and marketable securities resulting from investments in our WellCheck and WellCheck.com operations.

Income Taxes. We have significant net operating loss ("NOLs") and tax credit carryforwards. There was no provision for income taxes in fiscal 2001 due to the net operating loss. The \$129,000 provision for income taxes in fiscal 2000 represented the estimated federal and state alternative minimum taxes payable, reduced for the use of NOLs and tax credit carryforwards. Management expects to use NOLs and other tax carryforward amounts to the extent taxable income is earned in fiscal 2002 and beyond. Therefore, our effective tax rate should continue to be substantially less than the applicable statutory rates. As of March 30, 2001, we had NOL carryforwards of \$44.3 million available to reduce future taxable income for federal income tax purposes and NOL carryforwards of \$3.2 million available to reduce taxable income for state income tax purposes. Additionally, we had research and development and other tax credit carryforwards available to reduce income taxes for federal income tax purposes of \$1.9 million and research and development and other tax credit carryforwards available to reduce income taxes for state income tax purposes of \$768,000. We have historically experienced significant operating losses and operate in an industry subject to rapid technological changes. Therefore, management believes there is sufficient uncertainty regarding our ability to generate future taxable income and use these NOLs and tax credit carryforwards such that a full valuation allowance for deferred tax assets was required at March 30, 2001.

26

29

As a result of a change in our ownership which has occurred, there are annual limitations of approximately \$1.5 million for federal and state income tax purposes on the combined use of federal NOLs and federal and state tax credit carryforwards.

YEARS ENDED MARCH 31, 2000 AND MARCH 26, 1999

Revenue. Our total revenue increased 25.1% to \$27.5 million in fiscal 2000 from \$22.0 million in fiscal 1999. Diagnostic Products represented 98.5% of our total revenue in fiscal 2000 and 100% in fiscal 1999.

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

International revenue represented 17.6% of our total revenue in fiscal 2000, compared to 12.9% in fiscal 1999. In fiscal 2000 all international revenue related to the Diagnostic Products business unit.

Segment performance was as follows:

- Diagnostic Products revenue increased 22.5% to \$27.0 million in fiscal 2000 from \$22.0 million in fiscal 1999. The increase in revenue mainly reflected increased unit sales of single-use test cassettes in the physician office laboratory, health promotion and international markets. Unit sales of the L-D-X System declined in all domestic markets, other than international.
- WellCheck revenue totaled \$549,000 in fiscal 2000. All revenue since acquisition was earned during the last two fiscal months of fiscal 2000.
- WellCheck.com did not generate any revenue in fiscal 2000.

Cost of Revenue. Our cost of revenue increased 9.3% to \$11.2 million in fiscal 2000 from \$10.3 million in fiscal 1999. Gross margins were 59.3% in fiscal 2000 and 53.5% in fiscal 1999. Diagnostic Products accounted for 98.6% of our cost of products sold in fiscal 2000 and 100% in fiscal 1999.

Segment performance was as follows:

- Diagnostic Products cost of revenue includes direct labor, direct material, overhead and royalties. Cost of revenue increased 7.8% to \$11.1 million in fiscal 2000 from \$10.3 million in fiscal 1999. The increase in cost relating to the higher unit sales of single-use test cassettes was offset by reductions in indirect factory spending. Gross margins were 59.1% in fiscal 2000 and 53.5% in fiscal 1999. The gross margin improvement was primarily attributable to stronger spending controls.

We have licensed certain technology used in the manufacturing of certain of our products. A related agreement, which expires in 2006, requires us to pay a royalty of 2.0% on net sales of the applicable products. Total royalty expense was \$456,000 in fiscal 2000 and \$379,000 in fiscal 1999, and such amounts were charged to cost of revenue.

- WellCheck cost of revenue includes reimbursed travel expenses, laboratory services, medical waste disposal and the cost of medical testing equipment and supplies. Costs of product provided by the Diagnostic Products business are eliminated on consolidation. For the two months of operations in fiscal 2000, total cost of revenue was \$155,000.
- WellCheck.com cost of revenue will include costs related to the development and expansion of our two Internet-related software tools, TEAMS and WellCheck.com and amortization of capitalized website development costs.

Operating Expenses

Sales and Marketing. Our sales and marketing expense includes salaries, commissions, bonuses, expenses for outside services related to marketing programs and travel expenses. Sales and marketing expenses increased 6.4% to \$7.0 million in fiscal 2000 from \$6.6 million in fiscal 1999. Sales and marketing expenses decreased to 25.5% of revenue in fiscal 2000 from 30.0% in fiscal 1999. Diagnostic Products accounted for 97.2% of sales and marketing expenses for fiscal 2000 and 100% for fiscal 1999.

Sales and marketing expense in each of our segments was as follows:

- Diagnostic Products sales and marketing expense increased 3.3% to \$6.8 million in fiscal 2000 from \$6.6 million in fiscal 1999. The increase can be attributed primarily to the increased use of professional outside services. Sales and marketing expense decreased to 25.3% of revenue in fiscal 2000 from 30.0% of revenue in fiscal 1999. This change was partially impacted by the transfer of costs related to the former Executive Vice President of Marketing and Sales, who became the Chief Operating Officer of Diagnostic Products in October 1999 with associated costs thereafter reported on the general and administrative line of the Statement of Operations.
- WellCheck sales and marketing expense was \$200,000 in fiscal 2000. This business unit only operated during the last two months of fiscal 2000.
- WellCheck.com incurred no sales and marketing expense in fiscal 2000 as this business was still in the development stage.

Research and Development. Our research and development expense includes salaries, bonuses, expenses for outside services, supplies and amortization of capital equipment. Research and development expense increased 11.8% to \$3.0 million in fiscal 2000 from \$2.7 million in fiscal 1999. Research and development expenses as a percentage of revenue decreased to 11.0% in fiscal 2000 compared to 12.3% in fiscal 1999. Diagnostics Products accounted for 79.8% of research and development expense in fiscal 2000 and 100% in fiscal 1999. WellCheck.com incurred 20.2% of the research and development cost reported in fiscal 2000.

Research and development expense in each of our segments was as follows:

- Diagnostic Products research and development expense decreased 10.8% to \$2.4 million in fiscal 2000 from \$2.7 million in fiscal 1999. This reduction was mainly attributable to reduced head count and related expenses as the ALT single-use test cassette approached development completion. Research and development expense as a percentage of revenue decreased to 8.9% in fiscal 2000 compared to 12.3% in fiscal 1999.
- WellCheck incurred no research and development costs in fiscal 2000.
- WellCheck.com research and development expense was \$609,000 in fiscal 2000 net of \$2.0 million of capitalized website development costs. Activity occurred in the last six months of the year and was attributed to the design and development of the WellCheck.com website and TEAMS.

General and Administrative. Our general and administrative expense includes compensation and benefits, as well as expenses for outside professional services including information services, legal, accounting, our medical advisory board and costs associated with our board of directors. General and administrative expense increased by 47.4% to \$3.5 million in fiscal 2000 from \$2.4 million in fiscal 1999. General and administrative expense increased to 12.7% of revenue in fiscal 2000 from 10.8% in fiscal 1999. Diagnostics Products represented 67.5% of general and administrative expense in fiscal 2000 and 100% in fiscal 1999. WellCheck.com accounted for 25.5% and WellCheck accounted for 7% of general and administrative expense in fiscal 2000.

General and administrative expense in each of our segments was as follows:

- Diagnostic Products general and administrative expense remained relatively constant at \$2.4 million in both fiscal 2000 and fiscal 1999,

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

despite the addition of a Chief Operating Officer position. The addition of the Chief Operating Officer position and related expenses were offset by the partial allocation of corporate expenses to each of the other two business segments. General and administrative expense decreased to 8.8% of revenue in fiscal 2000, compared to 10.8% in fiscal 1999.

- WellCheck general and administrative expense was \$245,000 during the two months of operations since acquisition during fiscal 2000. In fiscal 2000 general and administrative expense was 44.6% of revenue.

28

31

- WellCheck.com general and administrative expense was \$896,000 during the final six months of fiscal 2000.

Goodwill Amortization. Goodwill amortization expense includes the costs relating to the amortization of capitalized costs associated with the purchase of Health Net in January 2000. In fiscal 2000 we recorded goodwill amortization of \$100,000. Our WellCheck business unit accounted for 100% of the expense.

Legal and Other Related. Our legal and related expense includes professional consulting fees, court related costs, and other fees relating to litigation. Legal and related expenses decreased by 73.5% to \$219,000 in fiscal 2000 from \$826,000 in fiscal 1999. Expenses incurred in fiscal 2000 include the defense of filed class action litigation and charges relating to the extension of certain employee stock options. During fiscal 1999, expenses included \$325,000 of fees relating to our withdrawn public stock offering, \$250,000 in settlement of litigation with a former employee, expenses associated with our reduction in force and legal expenses incurred to defend our company in a filed class action litigation.

Interest and Other Income, Net. Interest income reflects income from the investment of cash balances and marketable securities, net of expenses, relating to those investments. Interest income rose 21.4% to \$805,000 in fiscal 2000 from \$663,000 in fiscal 1999. This increase was the result of positive cash flows invested in marketable securities, as well as higher yields on securities.

Income Taxes. We have significant net operating loss carryforwards ("NOLs") and tax credit carryforwards. The \$129,000 provision for income taxes in fiscal 2000 represented the estimated federal and state alternative minimum taxes payable, reduced for the use of NOLs and tax credit carryforwards. Management expects to use NOLs and other tax carryforward amounts to the extent income is earned in fiscal 2001 and beyond. Therefore, our effective tax rate should continue to be substantially less than the applicable statutory rates. As of March 31, 2000, we had NOL carryforwards of \$41.2 million available to reduce future taxable income for federal income tax purposes and NOL carryforwards of \$867,000 available to reduce future taxable income for state income tax purposes. Additionally, we had research and development and other tax credit carryforwards available to reduce income taxes for federal income tax purposes of \$1.9 million and research and development and other tax credit carryforwards available to reduce income taxes for state income tax purposes of \$676,000. We have historically experienced significant operating losses and operate in an industry subject to rapid technological changes. Therefore, management believes there is sufficient uncertainty regarding our ability to generate future taxable income and use these NOLs and tax credit carryforwards such that a full valuation allowance for deferred tax assets was required at March 31, 2000.

As a result of a change in our ownership which occurred in May 1990, there is an annual limitation of approximately \$1.5 million for federal and state income tax purposes on the combined use of approximately \$6.1 million of federal NOLs and the use of \$550,000 of federal and state tax credit carryforwards.

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

Additionally, as a result of our public offering in December 1992, NOLs and tax credit carryforwards incurred before December 1992 are subject to an annual limitation of \$5.5 million for federal and state income tax purposes on the combined use of \$26.2 million of federal and \$4.5 million of state NOLs, and the use of \$1.2 million of federal and \$379,000 of state tax credit carryforwards. If the amounts of these limitations are not used in a particular year, the amount not used increases the limitation in the subsequent year.

LIQUIDITY AND CAPITAL RESOURCES

We have financed our operations primarily through the sale of equity securities and, in fiscal 2000 and fiscal 1998, from net income from operations. From inception to March 30, 2001, we raised \$72.8 million in net proceeds from equity financings. As of March 30, 2001, we had \$12.4 million of cash, cash equivalents and marketable securities. In addition to these amounts, we have available an \$8.0 million revolving bank line of credit agreement. While the agreement is in effect, we are required to deposit assets with a collective value, as defined in the line of credit agreement, equivalent to no less than 100% of the outstanding principal balance. Amounts outstanding under the line of credit bear interest at the bank's prime rate. The line of credit agreement expires on May 1, 2002. As of March 30, 2001, there were no borrowings outstanding under the line of credit.

29

32

During fiscal 2001, we generated \$2.3 million in cash from operating activities compared to generated cash of \$8.4 million in fiscal 2000. The cash provided during fiscal 2001 was composed mainly of a net loss of \$2.6 million and non-cash items of \$3.5 million in depreciation, impairment charges of \$1.96 million, provision for doubtful accounts of \$224,000 and inventory allowance of \$107,000, increased accrued payroll and benefits of \$337,000 and a decrease in prepaid and other accrued expenses of \$188,000. This was partially offset by a \$1.4 million increase in accounts receivable. The cash generated from operations in fiscal 2000 was primarily due to net income of \$3.1 million, increases in accounts payable and accrued liabilities of \$1.9 million, increases in accrued payroll and benefits of \$573,000, reductions in accounts receivable and inventory totaling \$1.4 million and depreciation and amortization of \$1.6 million, partially offset by increased prepaid expenses of \$756,000.

In fiscal 2001, we used \$5.8 million of cash in investing activities through the purchase of property and equipment of \$4.2 million, the final Health Net purchase payment of \$1.2 million and the net purchase of marketable securities of \$1.4 million, which was partially offset by the recovery of \$1.0 million of restricted cash. In fiscal 2000, net cash used by investing activities was \$8.5 million, consisting primarily purchases of property and equipment of \$4.2 million, the purchase of Health Net for \$2.3 million, the creation of \$1.0 million in restricted cash related to the final purchase price adjustment for the Health Net acquisition and the net purchase of marketable securities of \$957,000.

Net cash provided by financing activities was \$560,000 in fiscal 2001 as compared to \$1.4 million for fiscal 2000. For both years, cash provided by financing activities was primarily from the issuance of common stock pursuant to the employee stock purchase and employee stock incentive plans.

During fiscal 2002, we intend to expend approximately \$4.2 million for capital purchases related to expansion of our information technology systems, expansion of our manufacturing capacity and research and development.

QUARTERLY FINANCIAL DATA

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

| | QUARTER ENDED | | | | | |
|----------------------------|------------------|------------------|-------------------|------------------|------------------|--------------|
| | MAR. 30, 2001 | DEC. 29, 2000 | SEPT. 29, 2000 | JUNE 30, 2000 | MAR. 31, 2000 | DEC. 1999 |
| Revenue: | | | | | | |
| Previously reported..... | \$10,238 | \$8,850 | \$8,488 | \$8,888 | \$8,564 | \$6,7 |
| Reclassification..... | -- | -- | 229 | 311 | 127 | |
| Total revenue..... | 10,238 | 8,850 | 8,717 | 9,199 | 8,691 | 6,7 |
| Gross profit..... | 5,939 | 5,046 | 5,267 | 5,471 | 5,368 | 4,0 |
| Net income (loss)..... | \$(3,033) | \$(551) | \$ 29 | \$ 949 | \$1,477 | \$ 4 |
| Earnings (loss) per share: | | | | | | |
| Basic..... | \$ (0.25) | \$(0.05) | \$ 0.00 | \$ 0.08 | \$ 0.12 | \$ 0. |
| Diluted..... | \$ (0.25) | \$(0.05) | \$ 0.00 | \$ 0.08 | \$ 0.12 | \$ 0. |

Revenue and costs of revenue figures have been revised as a result of the retroactive adoption of EITF 00-10 "Accounting for Shipping and Handling Fees and Costs".

In the fourth quarter of fiscal 2001, we recorded an impairment charge of \$1.96 million in the WellCheck.com segment, for a write-off capitalized website and database development cost.

In the fourth quarter of fiscal 2001, we recorded additional legal and other charge of \$1.3 million in regards to resolving a class action lawsuit.

RECENT ACCOUNTING PRONOUNCEMENTS

In 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 on the balance sheet 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

30

33

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 the first quarter of 2001, the Financial Accounting Standards Board issued an Exposure Draft related to business combinations. If the final results are adopted as proposed, as of January 1, 2002, the Company will no longer be required to amortize goodwill as a charge to earnings. In addition, the Company will be required to periodically review goodwill for potential impairment. If an impairment is found to exist, a charge will be taken against earnings in the Company's consolidated statement of operations. The Company cannot currently determine the amount of an impairment charge, if any, that would be recorded upon adoption.

FACTORS AFFECTING FUTURE OPERATING RESULTS

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

WE HAVE NO PRIOR EXPERIENCE IN THE TESTING SERVICES BUSINESS, AND IF THIS NEW BUSINESS IS NOT SUCCESSFUL, WE WILL BE GREATLY HARMED.

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

OUR OPERATING RESULTS MAY SUFFER IF WE ARE UNABLE TO MANAGE GEOGRAPHICALLY DIVERSE OPERATIONS.

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

OUR NEW TESTING SERVICES BUSINESS REQUIRES SIGNIFICANT MANAGEMENT ATTENTION AND FINANCIAL RESOURCES TO DEVELOP AND IF THIS NEW BUSINESS IS NOT SUCCESSFUL, OUR BUSINESS WILL SUFFER.

The continued development of our new testing services business will require significant management attention and financial resources. These expenditures are likely to materially affect our operating results as a whole. We may need to seek additional capital to help fund these start-up expenses. The required additional capital may not be available to us at favorable or acceptable terms when required, or at all. If we cannot obtain required additional capital, we may have to change our business strategy, which would be disruptive to our business. If we raise additional capital through borrowings, the terms of such borrowings may impose limitations on how our management may operate the business in the future. If we raise additional capital by issuing equity, this may result in a dilution of existing shareholders' interests in us. Also, equity issued by us may have rights, preferences or privileges senior to those of our existing shareholders.

IF WE FAIL TO INTEGRATE ANY FUTURE ACQUISITIONS, OUR BUSINESS WILL BE HARMED.

We may use acquisitions of existing testing services businesses as a significant part of the development of our new testing business. These acquisitions could be very costly, could result in dilution to existing investors and could result in integration problems that harm the business as a whole. Any acquisition could result in expending significant amounts of cash, issuing potentially dilutive equity securities or incurring debt or amortization expenses related to goodwill and other intangible assets. Any of these acquisition financing approaches could materially harm our operating results and business. Acquisitions may also result in difficulties in assimilating the operations, technologies, products, services and personnel of the acquired

company or business. These difficulties could result in additional expenses and in diversion of management attention, which could prevent the new business from being successful. Any of these results could harm us financially.

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

OUR L-D-X SYSTEM HAS NOT YET ACHIEVED BROAD MARKET ACCEPTANCE IN ALL OF OUR TARGET MARKETS AND IF BROAD MARKET ACCEPTANCE DOES NOT OCCUR, OUR OPERATING RESULTS WILL BE HARMED.

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

- Low levels of awareness of the availability of our technology in both the physician and other customer groups;
- The L-D-X System's accuracy, ease of use, rapid test time, reliability and cost effectiveness compared to other testing alternatives;
- The growing prevalence of managed care may adversely affect the physician office laboratory market, as 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; and
- Limited availability and amount of reimbursement for performing tests on the L-D-X System.

If we do not achieve broad market acceptance, our Diagnostic Products business will not grow. Even if we are successful in continuing to place L-D-X Analyzers at physician office laboratories, 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 our single-use test cassettes. We are relying in significant part on income from the core Diagnostic Product business to finance our strategic expansion. If the Diagnostic Products business does not grow, the new business will not succeed. These results will cause severe financial harm to us.

As a result of these many hurdles to achieving broad market acceptance for the L-D-X System, demand for the L-D-X System may not be sufficient to sustain revenue and profits from operations. Because the L-D-X System currently contributes the vast majority of our revenue, we could be required to cease operations if the L-D-X System does not achieve and maintain a significant level of market acceptance.

OUR BUSINESS HAS EXPERIENCED A HISTORY OF OPERATING LOSSES AND FLUCTUATING OPERATING RESULTS, WHICH MAY CAUSE OUR STOCK PRICE TO FALL.

Historically, we have experienced significant operating losses and negative cash flows from operations. As of March 30, 2001, we had an accumulated deficit of \$48.0 million. Our 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 \$2.6 million for fiscal 2001. Our profitability and positive cash flows from operations in the future will require:

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

- Broadening market acceptance of our existing product offerings;
- Successfully developing, introducing and marketing additional test cassettes or other products for our Diagnostic Products business; and
- Successfully developing our new testing services business.

32

35

WE MAY EXPERIENCE SIGNIFICANT FLUCTUATIONS IN REVENUE 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 business;
- The timing and level of market acceptance of the L-D-X System;
- The timing of the introduction and availability of new tests;
- The timing and level of expenditures associated with research and development activities;
- The timing and level of expenditures associated with expansion of sales and marketing activities and overall operations;
- 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 our products based on changes in third party reimbursement, competition, changes in government regulation and other factors;
- The timing of significant orders from, and shipments, to customers;
- Product pricing and discounts;
- Variations in the mix of products sold; and
- General economic conditions.

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

IF WE DO NOT SUCCESSFULLY DEVELOP, INTRODUCE AND MARKET NEW TESTS, OUR BUSINESS

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

WILL BE HARMED.

Most of our revenue comes from our Diagnostics Products business. We anticipate this will continue for the near term. We also rely on revenue from the Diagnostics Products business to fund the development of our new testing services business. We believe our Diagnostic Products business will not grow significantly if we do not develop new tests to use with the L-D-X System. If new tests are not developed and accepted in the market, our business will not grow significantly and will be harmed. Developing new tests involves many significant problems and risks, including:

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

33

36

- New tests must meet a significant market need to be successful; and
- New tests must obtain proper regulatory approvals to be marketed.

We could experience difficulties that delay or prevent the successful development, introduction and marketing of new tests. For example, regulatory clearance or approval of any new tests may not be granted on a timely basis, or at all. We have experienced difficulties obtaining regulatory approval for tests in the past. Because the FDA's evaluation of applications for CLIA waived status is not based on precisely defined, objectively measurable criteria, we cannot predict the likelihood of obtaining waived status for future products.

WE FACE RISKS FROM FAILURES IN OUR MANUFACTURING PROCESSES.

We internally manufacture all of the single-use test cassettes that are used with the L-D-X Analyzer. The manufacture of single-use test cassettes is a highly complex and precise process that is sensitive to a wide variety of factors. We have, in the past, experienced lower than expected manufacturing yields that have adversely affected gross margins and delayed product shipments. If we do not maintain acceptable manufacturing yields of test cassettes or experience product shipment delays, our business, financial condition and results of operations could be materially adversely affected. We may reject or be unable to sell a substantial percentage of test cassettes because of:

- Raw materials variations or impurities;
- Manufacturing process variances and impurities; and
- Decreased manufacturing equipment performance.

Our cassette manufacturing lines would be costly and time consuming to repair or replace if their operation were interrupted. The interruption of our

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

manufacturing operations or the loss of employees dedicated to the manufacturing facility could severely harm our business. The risks involving our manufacturing lines include:

- As our production levels have increased, we have been required to use our machinery more hours per day and the down time resulting from equipment failure has increased;
- The custom nature of much of our manufacturing equipment increases the time required to remedy equipment failures and replace equipment;
- We have a limited number of employees dedicated to the operation and maintenance of our manufacturing equipment, the loss of whom could impact our ability to effectively operate and service such equipment; and
- We manufacture all cassettes at our Hayward, California manufacturing facility, so manufacturing operations are at risk to interruption from earthquake, fire, power outages or other events affecting this one location.

WE RELY ON A CONTINUOUS POWER SUPPLY TO CONDUCT OUR OPERATIONS, AND CALIFORNIA'S CURRENT ENERGY CRISIS COULD DISRUPT OUR OPERATIONS AND INCREASE OUR EXPENSES.

California is in the midst of an energy crisis that could disrupt our operations and increase our expenses. In the event of an acute power shortage (i.e. when power reserves for the State of California fall below 1.5%), California has on some occasions implemented, and may in the future continue to implement, rolling blackouts throughout California. We currently have backup generators to maintain only a limited amount of power and no alternate sources of power in the event of a prolonged blackout. Our current insurance does not provide coverage for any damages we or our customers may suffer as a result of any interruption in our power supply. If blackouts interrupt our power supply, we would be temporarily unable to continue operations at our facilities. Any such interruption in our ability to continue operations at our facilities could damage our reputation, harm our ability to retain existing customers and to obtain new customers and could result in lost revenue, any of which could substantially harm our business and results of operations.

34

37

OUR OPERATING RESULTS MAY SUFFER IF WE DO NOT REDUCE OUR MANUFACTURING COSTS.

We believe we will be required to reduce manufacturing costs for new and existing test cassettes to achieve sustained profitability. We currently operate two manufacturing lines for dry chemistry cassettes. We are installing and validating a third manufacturing line that is currently in preproduction validation and should be fully operational in July 2001. The complexity and custom nature of our manufacturing process increases the amount of time and money required to add an additional manufacturing line. Despite our efforts, the new manufacturing line may not 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.

OUR OPERATING RESULTS MAY SUFFER IF WE DO NOT DEVELOP NEW MANUFACTURING PROCESSES AND A NEW MANUFACTURING LINE TO MARKET IMMUNOASSAY TESTS IN DEVELOPMENT.

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

We may be required to build a new cassette manufacturing line 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. If we fail to successfully develop an immunoassay cassette manufacturing line and achieve acceptable yields we may not be able to cost-effectively satisfy customer orders. This development would have a material adverse effect on our business, financial condition and results of operations.

WE DEPEND ON SINGLE SOURCE SUPPLIERS FOR INPUTS TO OUR MANUFACTURING PROCESS AND FAILURE OF OUR SUPPLIERS TO PROVIDE SUPPLIES TO US COULD HARM OUR BUSINESS.

We currently depend on single source vendors to provide subassemblies, components and raw materials used in the manufacture of our products. Any supply interruption in a single source subassembly, component or raw material could restrict our ability to manufacture products until a new source of supply is identified and qualified. We may not be successful in qualifying additional sources of supply on a timely basis, or at all. Failure to obtain a usable alternative source could prevent us from manufacturing our products, resulting in inability to fill orders, customer dissatisfaction and loss of business. This would likely severely harm our business. In addition, an uncorrected impurity or supplier's variation in a raw material, either unknown to us or incompatible with our manufacturing process, could interfere with our ability to manufacture products. Because we are a small customer of many of our suppliers and we purchase their subassemblies, components and materials with purchase orders instead of long term commitments, our suppliers may not devote adequate resources to supplying our needs. Any interruption or reduction in the future supply of any subassemblies, components or raw materials currently obtained from single or limited sources could severely harm our business.

IF WE ARE SUCCESSFUL IN GROWING SALES, OUR BUSINESS WILL BE HARMED IF WE CANNOT EFFECTIVELY MANAGE THE OPERATIONAL AND MANAGEMENT CHALLENGES OF GROWTH.

If we are successful in achieving and maintaining market acceptance for the L-D-X System, we will be required to expand our operations, particularly in the areas of sales, marketing and manufacturing. As we expand our operations, this expansion will likely result in new and increased responsibilities for management personnel and place significant strain on our management, operating and financial systems and resources. To accommodate any such growth and compete effectively, we will be required to implement and improve our information systems, procedures and controls, and to expand, train, motivate and manage our work force. Our personnel, systems, procedures and controls may not be adequate to support our future operations. Any failure to implement and improve operational, financial and management systems or to manage our work force as required by future growth, if any, could harm our business and prevent us from improving our financial condition as a result of increased sales.

35

38

WE DEPEND ON DISTRIBUTORS TO SELL OUR PRODUCTS, AND HAVE HAD DIFFICULTY IN THE PAST MAINTAINING SOME DISTRIBUTOR RELATIONSHIPS.

To increase revenue and achieve sustained profitability, we will have to maintain and expand our existing distribution relationships and develop new distribution relationships. We are dependent on such distributors to assist us in promoting market acceptance of the L-D-X System. If we do not maintain and expand these relationships, our sales will not grow and our business will be greatly harmed. We have in the past had problems maintaining relationships with our distributors to the pharmacy market. Distribution agreements with AmeriSource Health Corporation and Bergen Brunswig Corporation, both national distributors to the pharmacy market, were cancelled due to contractual

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

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.

WE RELY ON A LIMITED NUMBER OF CUSTOMERS FOR A SUBSTANTIAL PART OF OUR REVENUE.

Sales to a limited number of customers have accounted for a significant portion of our revenue in each fiscal period. We have experienced periods in which sales to some of our major customers, as a percentage of total revenue, have fluctuated due to delays or failures to place expected orders. We expect that sales to a limited number of customers will continue to account for a substantial portion of our total revenue in future periods. In fiscal 2000, Physician Sales and Service, Inc. accounted for approximately 16.9 % of our total revenue and GMR accounted for less than 1% of our total revenue. In fiscal 2001, Physician Sales and Service, Inc. accounted for approximately 16.4% of our total revenue and GMR accounted for approximately 7.4% of our total revenue. We do not have long-term agreements with any of our customers. Customers generally purchase our products pursuant to cancelable short-term purchase orders. Our results of operations have been negatively affected in the past by the failure of anticipated orders to materialize and by delays in or cancellations of orders. If we were to lose a major customer or if orders by or shipments to a major customer were to otherwise decrease or be delayed, our results of operations would be harmed.

IF THIRD PARTY REIMBURSEMENT FOR USE OF OUR PRODUCTS IS ELIMINATED OR REDUCED, OUR SALES WILL BE GREATLY REDUCED AND OUR BUSINESS MAY FAIL.

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

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

- Third party payors increasingly scrutinize and challenge the prices charged for medical products and services;
- Healthcare providers are moving toward a managed care system in which they provide comprehensive healthcare for a fixed cost per patient and authorize fewer elective procedures, such as uses of our products for diagnostic screening;
- General uncertainty regarding what changes will be made in the reimbursement methods used by third party payors and how that will affect use of products such as ours, which may deter healthcare providers from adopting the use of our products; and

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

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

Market acceptance of our products in international markets is also dependent, in part, on the availability of reimbursement within prevailing healthcare systems. Reimbursement and healthcare systems in international markets vary significantly by country and include both government sponsored healthcare and private insurance. Third party reimbursement and coverage may not be available or adequate in either the United States or international markets, and current reimbursement amounts may be decreased in the future. Also, future legislation, regulation or reimbursement policies of third party payors may adversely affect demand for our products or our ability to sell our products on a profitable basis. Any of these events could materially harm our business. See "Business -- Third Party Reimbursement."

IF THE HEALTHCARE SYSTEM IN THE UNITED STATES UNDERGOES FUNDAMENTAL CHANGE, THESE CHANGES MAY HARM OUR BUSINESS.

We believe the healthcare industry in the United States is likely to undergo fundamental changes due to current political, economic and regulatory influences. We anticipate that Congress, state legislatures and the private sector will continue to review and assess alternative healthcare delivery and payment systems. Potential alternatives include mandated basic healthcare benefits, controls on healthcare spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, the creation of large insurance purchasing groups, price controls and other fundamental changes to the healthcare delivery system. We expect legislative debate to continue in the future and for market forces to demand reduced costs. We cannot predict what impact the adoption of any federal or state health care reform measures, future private sector reform or market forces may have on our business. Any changes in the healthcare system could potentially have extremely negative effects on our business.

OUR PRODUCTS ARE SUBJECT TO MULTIPLE LEVELS OF GOVERNMENT REGULATION AND ANY REGULATORY CHANGES ARE DIFFICULT TO PREDICT AND COULD BE DAMAGING TO OUR BUSINESS.

The manufacture and sale of our diagnostic products, including the L-D-X System, are subject to extensive regulation by numerous governmental authorities, principally the Food and Drug Administration and corresponding state and foreign regulatory agencies. We are not able to commence marketing or commercial sales in the United States of any of the new tests we develop until we receive required clearances and approvals. The process of obtaining required regulatory clearances and approvals is lengthy, expensive and uncertain. As a result, our new tests under development, even if successfully developed, may never obtain such clearance or approval. Additionally, certain material changes to products that have already been cleared or approved are subject to further review and clearance or approval. Medical devices are subject to continual review, and later discovery of previously unknown problems with a cleared product may result in restrictions on the product's marketing or withdrawal of the product from the market. If we lose previously obtained clearances, or fail to comply with existing or future regulatory requirements, we may not be able to market the affected products, which would depress our revenue and severely harm our business.

In addition, any future amendment of or addition to regulations impacting our products could prevent us from marketing the L-D-X System. Regulatory changes could hurt our business by increasing burdens on our products or by reducing or eliminating certain competitive advantages of the L-D-X System's waived status.

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

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

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

37

40

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

The use of our products and those of our competitors is also affected by federal and state regulations, which provide for regulation of laboratory testing, as well as by the laws and regulations of foreign countries. The scope of these regulations includes quality control, proficiency testing, personnel standards and inspections. In the United States, clinical laboratory testing is regulated under the Clinical Laboratory Improvement Act of 1976. The L-D-X Analyzer, our total cholesterol, high density lipoproteins, triglycerides and glucose tests in any combination and our ALT test cassette have been classified as waived from the application of many of the requirements under the Clinical Laboratory Improvement Act. We believe this waived classification is critical for our products to be successful in their markets. Any failure of our new tests to obtain waived status under the Clinical Laboratory Improvement Act will severely limit our ability to commercialize such tests. Loss of waived status for existing diagnostic products or failure to obtain waived status for new products could limit our sales and revenue, which would severely harm our business.

WE MAY FACE FINES OR OUR MANUFACTURING FACILITIES COULD BE CLOSED IF WE FAIL TO COMPLY WITH MANUFACTURING AND ENVIRONMENTAL REGULATIONS.

Our manufacturing processes and, in certain instances, those of our contract manufacturers, are subject to stringent federal, state and local regulations governing the use, generation, manufacture, storage, handling and disposal of certain materials and wastes. Failure to comply with present or future regulations could result in many things, including warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal of the government to grant pre-market clearance or pre-market approval for devices, withdrawal of approvals and criminal prosecution. Any of these could harm our business. We and our contract manufacturers are also subject to federal, state and foreign regulations regarding the manufacture of healthcare products and diagnostic devices, including:

- Quality system regulations, which requires the maintenance of a quality system consistent with FDA regulations;
- ISO9001/EN46001 requirements, which is an industry standard for maintaining and assuring conformance to quality standards; and
- Other foreign regulations and state and local health, safety and environmental regulations, which include testing, control and documentation requirements.

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

Changes in existing regulations or adoption of new governmental regulations or policies could prevent or delay regulatory approval of our products or require us to incur significant costs to comply with manufacturing and environmental regulations, which could harm our business.

OUR BUSINESS DEPENDS ON OUR ABILITY TO PROTECT OUR PROPRIETARY TECHNOLOGY THROUGH PATENTS AND OTHER MEANS, WHICH MAY NOT BE SUCCESSFUL OR MAY REQUIRE COSTLY LITIGATION TO ENFORCE.

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

- Our pending patent applications may not result in the issuance of any patents, or, if issued, such patents may not offer protection against competitors with similar technology;
- Our patents may be challenged, invalidated or circumvented in the future, and the rights created under our patents may not provide a competitive advantage;
- Competitors, many of 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

38

41

uncompetitive or could prevent, limit or interfere with our ability to make, use or sell our products either in the United States or in international markets;

- The medical products industry has been characterized by extensive litigation regarding patents and other intellectual property rights; and
- An adverse determination in litigation or interference proceedings to which we may become a party could subject us to significant liabilities to third parties or require us to seek licenses from third parties, which may not be available on commercially reasonable terms or at all.

We may in the future become subject to patent infringement claims and litigation or interference proceedings conducted in the United States Patent and Trademark Office to determine the priority of inventions. Litigation may also be necessary to enforce any patents issued to us, to protect our trade secrets or know-how or to determine the enforceability, scope and validity of the proprietary rights of others. The defense and prosecution of intellectual property suits, patent interference proceedings and related legal and administrative proceedings are both costly and time consuming and will likely result in substantial diversion of attention of technical and management personnel.

In the past, patent infringement claims have been asserted against us. In December 1999, an injunction was filed in Zug, Switzerland by Roche Diagnostics, a subsidiary of Roche Holdings, Ltd., seeking a cease and desist order barring us and two of our distributors from distributing HDL assay single-use test cassettes in Switzerland. The complaint alleges that we violated a Roche European patent for HDL. The court is expected to reach a decision on the merits

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

of the complaint in the next several months. Additionally, in January 2000, a complaint was filed in the District Court, Dusseldorf, Germany against us and two of our distributors seeking a cease and desist order barring the distributors from shipping HDL single-use test cassettes into Germany. The complaint alleges we and our distributors violated a Roche German priority patent for HDL by selling our single-use test cassette containing a HDL assay. The court has requested additional information be submitted by both parties, but has not made any ruling or set additional court dates. In September 2000, we were served a complaint, No. Ei/Ti ROCH 04002, filed in Vienna, Austria by Roche Diagnostics, seeking a cease and desist order barring us and one of our distributors from distributing HDL assay single-use test cassettes in Austria. The complaint alleges that we violated a Roche European patent for HDL. At this point, no schedule has been set regarding court activity. We believe all suits are without merit and intend to defend the cases vigorously. We do not believe that we engaged in any wrongdoing and that the outcome of this matter will not result in a material adverse effect; however, there can be no assurance that the lawsuits will be resolved in our favor.

We rely on trade secrets, technical know-how and continuing invention to develop and maintain our competitive position. Others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technology. We may also not be able to meaningfully protect our right to our trade secrets.

WE DEPEND ON TECHNOLOGY THAT WE LICENSE FROM OTHERS, WHICH MAY NOT BE AVAILABLE TO US IN THE FUTURE AND WOULD PREVENT US FROM PRODUCING OUR PRODUCTS AND SEVERELY HARM OUR BUSINESS.

Our current products incorporate technologies which are the subject of patents issued to, and patent applications filed by, others. We have obtained licenses for certain of these technologies. We may in the future be required to obtain licenses for new products. We may not be able to obtain licenses for technology patented by others on commercially reasonable terms, or at all. We also may not be able to develop alternative approaches if we are unable to obtain licenses. Also, our current and future licenses may not be adequate for the operation of our business. Failure to obtain adequate licenses on commercially reasonable terms could prevent us from producing our products and severely harm our business.

39

42

WE MAY NOT BE ABLE TO EFFECTIVELY COMPETE AGAINST OTHER PROVIDERS OF DIAGNOSTIC PRODUCTS AND TESTING SERVICES, WHICH COULD CAUSE OUR SALES TO DECLINE.

The markets for diagnostic products and testing services in which we operate are intensely competitive. Our competition consists mainly of clinical and hospital laboratories, as well as manufacturers of bench top analyzers. To achieve market acceptance for the L-D-X System, we must demonstrate that the L-D-X System is an attractive alternative to bench top analyzers as well as to clinical and hospital laboratories. This will require physicians to change their established means of having such tests performed. The L-D-X System may not be able to compete with these other testing services and analyzers. In addition, companies having a significant presence in the market for therapeutic monitoring, such as Abbott Laboratories, Beckman Coulter, Inc. and Roche Diagnostics, (a subsidiary of Roche Holding, Ltd.) have developed or are developing analyzers designed for near-patient testing. These competitors have substantially greater financial, technical, research and other resources and larger, more established marketing, sales, distribution and service organizations than us. These competitors also offer broader product lines than us, have greater name recognition than us and offer discounts as a competitive tactic. In addition, several smaller companies are currently making or

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

developing products that compete or will compete with ours. We may not have the financial resources, technical expertise or marketing, distribution or support capabilities to compete successfully in the future. Even if we do have such resources and capabilities, we may not employ them successfully.

FAILURE TO RETAIN OUR KEY PERSONNEL AND ATTRACT ADDITIONAL QUALIFIED EMPLOYEES COULD HURT OUR OPERATIONS.

Our success depends in significant part on the continued service of certain key scientific, technical, regulatory and managerial personnel. Our success will also require us to continue to attract and retain additional highly qualified personnel in those areas. Competition for qualified personnel is intense, particularly in the San Francisco Bay Area where we are located, because of the number of attractive technology employment opportunities and the extremely high cost of living. We may not be able to retain our key personnel or attract or retain other necessary highly qualified personnel in the future. If we do not keep our key personnel or attract other needed employees, we will not be able to grow our business.

SALE OF OUR DIAGNOSTIC PRODUCTS AND PERFORMANCE OF OUR SERVICES MAY SUBJECT US TO LIABILITY CLAIMS, AND IF OUR INSURANCE IS INSUFFICIENT, THIS LIABILITY COULD SEVERELY HARM OUR BUSINESS.

Sale of our products and performance of our testing services entail risk of product and professional claims. If any of these claims are brought, we may have to expend significant resources defending against them. If we are found liable for any of these claims, we may have to pay damages that could severely hurt our financial position. Loss of these claims could also hurt our reputation, resulting in our losing business and market share. The medical testing industry has historically been litigious, and we face financial exposure to these liability claims if use of our products results in personal injury or improper diagnosis. We also face the possibility that defects in the design or manufacture of our products might necessitate a product recall.

We currently maintain product liability professional liability insurance, but there can be no assurance that the coverage limits of our insurance policies will be adequate. Insurance is expensive and difficult to obtain, and product liability insurance may not be able to be maintained in the future on acceptable terms, in sufficient amounts to protect us against losses due to product liability. Inability to maintain insurance at an acceptable cost or to otherwise protect against potential product liability could prevent or inhibit the continued commercialization of our products. In addition, a product liability claim in excess of relevant insurance coverage or a product recall could severely hurt our financial condition.

WE MAY NEED ADDITIONAL CAPITAL IN THE FUTURE TO SUPPORT OUR GROWTH, AND SUCH ADDITIONAL FUNDS MAY NOT BE AVAILABLE TO US.

We intend to expend substantial funds for capital expenditures related to expansion of our manufacturing capacity, research and development, expansion of sales and marketing activities and other working capital and general corporate purposes. Also, we plan to expend significant amounts in developing our new testing services business. Although we believe our cash, cash equivalents, marketable securities, cash flow anticipated to be

generated by future operations and available bank borrowings under an existing line of credit will be sufficient to meet our operating requirements for the foreseeable future, we may still require additional financing. For example, we may be required to expend greater than anticipated funds if unforeseen

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

difficulties arise in expanding manufacturing capacity for existing cassettes or in the course of completing required additional development, obtaining necessary regulatory approvals, obtaining waived status under CLIA or introducing or scaling up manufacturing for new tests. Developing our new testing services business may also require more capital than we currently anticipate. This possibility is increased given our lack of experience in the markets addressed by this new business.

If additional financing is needed, we may seek to raise additional funds through public or private financing, collaborative relationships or other arrangements. Any additional equity financing may be dilutive to shareholders and debt financing, if available, may involve restrictive covenants. Collaborative arrangements, if necessary to raise additional funds, may require us to relinquish our rights to technologies, products or marketing territories. Our failure to raise capital on acceptable terms when needed could prevent us from developing our products and our business.

WE HAVE MADE USE OF DEVICES TO LIMIT THE POSSIBILITY THAT WE ARE ACQUIRED, WHICH MAY MEAN THAT A TRANSACTION THAT SHAREHOLDERS ARE IN FAVOR OF OR ARE BENEFITED BY MAY BE PREVENTED.

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

OUR STOCK PRICE IS LIKELY TO CONTINUE TO BE VOLATILE, WHICH COULD RESULT IN SUBSTANTIAL LOSSES FOR INVESTORS.

The market price of our stock has in the past been, and is likely in the future to continue to be, highly volatile. These fluctuations could result in substantial losses for investors. Factors that cause our stock price to fluctuate include:

- Quarterly variations in our operating results;
- Announcements by us and our competitors of technological innovations or new commercial products;
- Government regulation;
- Changes in the current structure of the healthcare financing and payment systems;
- Developments in or disputes regarding patent or other proprietary rights;
- Stock market price and volume fluctuations, which have particularly affected the market prices for medical products and high technology companies and which are often been unrelated to the operating performance of such companies; and
- General economic, political and market conditions.

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

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

41

44

IF THIRD PARTY SPONSORSHIP OF OUR TESTING SERVICES BUSINESS IS ELIMINATED OR REDUCED, OUR REVENUE WILL BE GREATLY REDUCED AND OUR BUSINESS MAY FAIL.

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

WE MUST LOCATE AN ADEQUATE NUMBER OF TESTING VENUES FOR THE TESTING SERVICES BUSINESS.

For our testing services business to succeed, we must maintain the current number of testing sites and find a greater number of locations and more diverse venues to perform consumer testing. We must convince operators of the venues of the testing services' economic benefits. If the number of testing sites do not increase or are reduced, our business could be harmed.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

QUANTITATIVE DISCLOSURES

Our exposure to market risks is inherent in our operations, primarily to interest rates relating to our investment portfolio. We do not use derivative financial instruments in our investment portfolio and had no holdings of derivative financial or commodity instruments at March 30, 2001.

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

We have concluded that the fair market value of our investment portfolio or related income would not be significantly impacted by changes in interest rates due to the nature of our marketable securities, which do not exceed fiscal 2003 and have primarily fixed interest rates.

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

| | 2002 | 2003 | TOTAL | FAIR VALUE |
|-----------------------------|----------------|-------|---------|------------|
| | ----- | ----- | ----- | ----- |
| | (IN THOUSANDS) | | | |
| Cash, cash equivalents..... | \$4,052 | \$ -- | \$4,052 | \$4,052 |

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

| | | | | |
|---------------------------------------|---------|---------|---------|---------|
| Short-term marketable securities..... | \$4,697 | -- | \$4,697 | \$4,697 |
| Weighted average interest rate..... | 5.47% | -- | -- | -- |
| Long-term marketable securities..... | \$ -- | \$3,616 | \$3,616 | \$3,616 |
| Weighted average interest rate..... | -- | 5.95% | -- | -- |

QUALITATIVE DISCLOSURES

Interest Rate Risk.

Our primary interest rate risk exposures relate to:

- The available for sale securities will fall in value if market interest rates increase.
- The impact of interest rate movements on our ability to obtain adequate financing to fund future operations.

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

42

45

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated financial statements and the independent auditors' report appear on pages F-1 through F-22 of this Report. See Item 14 for an index of financial statements and supplementary data.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

43

46

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information required by this item concerning our directors is incorporated by reference from the sections captioned "Election of Directors" and "Section 16(a) Beneficial Ownership Reporting Compliance" contained in the Company's Proxy Statement related to the 2001 Annual Meeting of Shareholders to be held August 16, 2001, to be filed by us within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K (the "Proxy Statement"). Certain information required by this item concerning executive officers set forth in Part I of this Report under information required "Business -- Executive Officers" and certain other information required by this item is incorporated by reference from the section captioned "Section 16(a) Beneficial Ownership Reporting Compliance" contained in the Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference from the section captioned "Executive Compensation and Other Matters" contained in the Proxy Statement.

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information required by this item is incorporated by reference from the section captioned "Record Date and Principal Share Ownership" contained in the Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this item is incorporated by reference from the sections captioned "Compensation Committee Interlocks and Insider Participation" and "Certain Transactions" contained in the Proxy Statement.

PART IV

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

(a) (1) Financial Statements

The following consolidated financial statements are filed as part of this Report:

| | PAGE |
|--|------|
| | ---- |
| Report of Independent Accountants..... | F-1 |
| Consolidated Balance Sheets..... | F-2 |
| Consolidated Statements of Operations..... | F-3 |
| Consolidated Statement of Changes in Shareholders' Equity... | F-4 |
| Consolidated Statements of Cash Flows..... | F-5 |
| Notes to Consolidated Financial Statements..... | F-6 |

(a) (2) Financial Statement Schedules

| | |
|---|------|
| Schedule II -- Valuation and Qualifying Accounts..... | F-20 |
|---|------|

All other schedules are omitted because they are not applicable or the required information is shown in the consolidated financial statements or notes thereto.

44

47

(a) (3) Exhibits

| | |
|---------|--|
| 3.1(1) | Restated Articles of Incorporation of Registrant |
| 3.2(2) | Bylaws of Registrant, as amended |
| 4.2(3) | Preferred Share Rights Agreement dated January 22, 1997 between Registrant and Chase Mellon Shareholder Services, L.L.C., including the Certificate of Determination, the form of Rights Certificate and Summary of Rights attached thereto as Exhibits A, B and C, respectively |
| 10.1(4) | 1988 Stock Incentive Program and forms of agreements thereunder |

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

| | |
|-------------|---|
| 10.2(5) | 1992 Employee Stock Purchase Plan |
| 10.3(2) | Standard Industrial Lease Agreement between Registrant and Sunlife Assurance Company of Canada dated October 22, 1989 |
| 10.3.1(6) | First Amendment to Standard Industrial Lease Agreement between Registrant and Sunlife Assurance Company of Canada dated April, 1995 |
| 10.4(2) | Forms of Indemnification Agreements between Registrant and its officers and its directors |
| 10.5 | Reserved |
| 10.6 | Reserved |
| 10.6.1 | Reserved |
| 10.7 | Reserved |
| 10.7.1 | Reserved |
| 10.8 | Reserved |
| 10.9 | Reserved |
| 10.10 | Reserved |
| 10.11.1 | Reserved |
| 10.11.2 | Reserved |
| 10.11.3 | Reserved |
| 10.11.4 | Reserved |
| 10.11.5 | Reserved |
| 10.11.6 | Reserved |
| 10.11.7 | Reserved |
| 10.12 | Reserved |
| 10.13 | Reserved |
| 10.14 | Reserved |
| 10.15 | Reserved |
| 10.16 | Reserved |
| 10.17.1(7) | Letter Agreement effective December 20, 1996 by and between Wells Fargo Bank and Registrant |
| 10.17.2(7) | Revolving Line of Credit Note effective December 20, 1996 by and between Wells Fargo Bank and Registrant |
| 10.17.3(7) | General Pledge Agreement effective December 20, 1996 by and between Wells Fargo Bank and Registrant |
| 10.17.4(8) | Revolving Line of Credit Note effective November 30, 1997 by and between Wells Fargo Bank and Registrant |
| 10.17.5(9) | Revolving Line of Credit Note effective November 30, 1998 by and between Wells Fargo Bank and Registrant |
| 10.17.6(10) | Revolving line of Credit Note Effective November 30, 1999 by and between Wells Fargo Bank and Registrant |
| 10.17.7(11) | Revolving line of Credit Note effective May 1, 2000 by and between Wells Fargo Bank and Registrant |
| 10.18 | Reserved |
| 10.19 | Reserved |
| 10.20(12) | 1997 Stock Incentive Program and Form of Agreement thereunder |

| | |
|-------------|---|
| 10.21(13) | 1999 Nonstatutory Stock Option Plan and Form of Agreement thereunder |
| 10.21.1(14) | Distribution Agreement between Registrant and McKesson Drug Company dated August 18, 1998 |
| 10.21.2(14) | Distribution Agreement between Registrant and Bergen Brunswig Corporation dated July 20, 1998 |
| 10.22 | Reserved |
| 10.23(15) | Employment Agreement between Registrant and Robert J. Dominici dated July 15, 1998 |
| 10.24(16) | Employment Agreement between Registrant and Jeffrey S. Aroy |

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

| | |
|-----------|---|
| | dated September 3, 1999 |
| 10.25(11) | Employment Agreement between Registrant and Thomas E. Worthy dated August 6, 1999 |
| 10.26(11) | Employment Agreement between Registrant and Terry L. Wassmann dated March 28, 2000 |
| 10.27(11) | Employment Agreement between Registrant and Kevin R. Stromberg dated March 27, 2000 |
| 10.28(11) | Employment Agreement between Registrant and Timothy I. Still dated October 6, 1999 |
| 10.29(17) | 2000 Stock Incentive Program and Form of Agreement thereunder |
| 10.30* | Letter Agreement between Registrant and GMR Marketing, Inc. dated January 23, 2001 |
| 10.31 | Amendment to the Letter Agreement between Registrant and GMR Marketing, Inc. dated April 30, 2001 |
| 10.32 | Employment Agreement between Registrant and William W. Burke dated March 14, 2001 |
| 10.33 | Lease Agreement between Registrant and Terradev Jefferson LLC dated July 28, 2000 |
| 10.34 | Second Amendment to Standard Industrial Lease Agreement between Registrant and Sunlife Assurance Company of Canada dated March 17, 1995 |
| 10.35 | Third Amendment to Standard Industrial Lease Agreement between Registrant and Sunlife Assurance Company of Canada dated January 27, 1997 |
| 10.36 | Fourth Amendment to Standard Industrial Lease Agreement between Registrant and The BIV Group (successor-in-interest to Sunlife Assurance Company of Canada) dated March 3, 2000 |
| 10.3.2 | Reserved |
| 10.3.3 | Reserved |
| 21.1 | Subsidiaries |
| 23.1 | Consent of Independent Accountants |

* Confidential treatment has been requested from the Securities and Exchange Commission with respect to certain portions of this exhibit. The redacted portions have been filed separately with the Securities and Exchange Commission.

- (1) Incorporated by reference to exhibits filed with Registrant's Registration Statement on Form S-1 (No. 33-54300) as declared effective by the Securities and Exchange Commission on December 16, 1992.
- (2) Incorporated by reference to exhibits filed with Registrant's Registration Statement on Form S-1 (No. 33-47603) as declared effective by the Securities and Exchange Commission on June 26, 1992.
- (3) Incorporated by reference to exhibits filed with Registrant's Registration Statement on Form 8-A (No. 000-20198) as declared effective by the Securities and Exchange Commission on March 27, 1997.
- (4) Incorporated by reference to exhibits filed with Registrant's Registration Statement on Form S-8 (No. 333-22475) as declared effective by the Securities and Exchange Commission on February 28, 1997.
- (5) Incorporated by reference to exhibits filed with Registrant's Registration Statement on Form S-8 (No. 333-38147) as declared effective by the Securities and Exchange Commission on October 17,

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

1997, as amended by Registrant's Registration Statement on Form S-8 (No. 333-38147) as declared effective by the Securities and Exchange Commission on October 17, 1997, as amended by Registrant's Registration Statement on Form S-8 (No. 333-44980) as declared effective by the Securities and Exchange Commission on August 31, 2000.

- (6) Incorporated by reference to exhibits filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1995.
- (7) Incorporated by reference to exhibits filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended December 27, 1996.
- (8) Incorporated by reference to exhibits filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended December 26, 1997.
- (9) Incorporated by reference to exhibits filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended December 25, 1998.
- (10) Incorporated by reference to exhibits filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended December 24, 1999.
- (11) Incorporated by reference to exhibits filed with Registrant's Annual Report on Form 10-K for the fiscal year ended March 31, 2000.
- (12) Incorporated by reference to exhibits filed with Registrant's Registration Statement on Form S-8 (No. 333-38151) as declared effective by the Securities and Exchange Commission on October 17, 1997.
- (13) Incorporated by reference to exhibits filed with Registrant's Registration Statement on Form S-8 (No. 333-94503) as declared effective by the Securities and Exchange Commission on January 12, 2000.
- (14) Incorporated by reference to exhibits filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended September 25, 1998.
- (15) Incorporated by reference to exhibits filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended June 25, 1999.
- (16) Incorporated by reference to exhibits filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended September 24, 1999.
- (17) Incorporated by reference to exhibits filed with Registrant's Registration Statement on Form S-8 (333-44980) as declared effective by the Securities and Exchange Commission on August 31, 2000.

(b) Reports on Form 8-K. The Company did not file any reports on Form 8-K during the quarter ended March 30, 2001.

(c) Exhibits. See Item 14(a)(3) above.

(d) Financial Statement Schedules. See Item 14(a)(2) above.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

CHOLESTECH CORPORATION

By: /s/ WARREN E. PINCKERT II

Warren E. Pinckert II
President, Chief Executive Officer
and Director

Date: June 14, 2001

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Warren E. Pinckert II and William W. Burke, and each of them, his or her true and lawful attorneys-in-fact and agents, each with full power of substitution and resubstitution, to sign any and all amendments (including post-effective amendments) to this Annual Report on Form 10-K and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their substitute or substitutes, or any of them, shall do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities and Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant and in the capabilities and on the dates indicated:

| SIGNATURE ----- | TITLE ----- | DATE ----- |
|---|--|---------------|
| /s/ WARREN E. PINCKERT II ----- (Warren E. Pinckert II) | President, Chief Executive Officer and Director (Principal Executive Officer) | June 14, |
| /s/ WILLIAM W. BURKE ----- (William W. Burke) | Vice President of Finance, Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer) | June 14, |
| /s/ JOHN H. LANDON ----- (John H. Landon) | Director | June 14, |
| /s/ MICHAEL D. CASEY ----- (Michael D. Casey) | Director | June 14, |
| /s/ JOHN L. CASTELLO ----- (John L. Castello) | Director | June 14, |
| /s/ MOLLY J. COYE ----- (Molly J. Coye) | Director | June 14, |

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

/s/ LARRY Y. WILSON

Director

June 14,

(Larry Y. Wilson)

48

51

REPORT OF INDEPENDENT ACCOUNTANTS

To the Board of Directors and
Shareholders of Cholestech Corporation

In our opinion, the consolidated financial statements listed in the index appearing under Item 14(a)(1) present fairly, in all material respects, the financial position of Cholestech Corporation and its subsidiaries at March 30, 2001 and March 31, 2000, and the results of their operations and their cash flows for each of the three years in the period ended March 30, 2001 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the index appearing under Item 14(a)(2) presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. These financial statements and financial statement schedule are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PRICEWATERHOUSECOOPERS LLP

San Jose, California
April 20, 2001, except for the fourth paragraph
of Note 5, which is as of June 14, 2001

F-1

52

CHOLESTECH CORPORATION

CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS, EXCEPT SHARE DATA)

| | MARCH 30, 2001 | MARCH 31, 2000 |
|--|----------------|----------------|
| | ----- | ----- |
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents..... | \$ 4,052 | \$ 6,959 |
| Restricted cash..... | -- | 1,000 |
| Marketable securities..... | 4,697 | 2,850 |
| Accounts receivable, net..... | 3,014 | 1,839 |
| Inventories, net..... | 3,658 | 3,714 |
| Prepaid expenses and other assets..... | 717 | 902 |

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

| | | |
|----------------------------------|-----------|-----------|
| Total current assets..... | 16,138 | 17,264 |
| Property and equipment, net..... | 7,777 | 8,309 |
| Long-term investments..... | 3,616 | 3,932 |
| Goodwill, net..... | 3,143 | 2,661 |
| Other assets, net..... | 68 | 52 |
| | ----- | ----- |
| Total assets..... | \$ 30,742 | \$ 32,218 |
| | ===== | ===== |

LIABILITIES AND SHAREHOLDERS' EQUITY

| | | |
|---|-----------|-----------|
| Current liabilities: | | |
| Accounts payable and accrued expenses..... | \$ 3,893 | \$ 3,788 |
| Accrued payroll and benefits..... | 1,900 | 1,563 |
| Other liabilities..... | 91 | 391 |
| | ----- | ----- |
| Total current liabilities..... | 5,884 | 5,742 |
| | ----- | ----- |
| Commitments and contingencies (Note 5) | | |
| Shareholders' equity: | | |
| Preferred Stock, no par value; 5,000,000 shares authorized, no shares issued and outstanding..... | -- | -- |
| Common Stock, no par value; 25,000,000 shares authorized; 12,100,647 and 11,921,251 shares issued and outstanding at March 30, 2001 and March 31, 2000..... | 72,819 | 71,959 |
| Accumulated other comprehensive income (loss)..... | 69 | (59) |
| Accumulated deficit..... | (48,030) | (45,424) |
| | ----- | ----- |
| Total shareholders' equity..... | 24,858 | 26,476 |
| | ----- | ----- |
| Total liabilities and shareholders' equity..... | \$ 30,742 | \$ 32,218 |
| | ===== | ===== |

See accompanying notes to consolidated financial statements.

F-2

53

CHOLESTECH CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS
(IN THOUSANDS, EXCEPT PER SHARE DATA)

| | FISCAL YEAR ENDED | | |
|--------------------|-------------------|-------------------|-------------------|
| | MARCH 30, 2001 | MARCH 31, 2000 | MARCH 26, 1999 |
| | ----- | ----- | ----- |
| Revenue: | | | |
| Product..... | \$32,489 | \$27,000 | \$22,032 |
| Service..... | 4,514 | 549 | -- |
| | ----- | ----- | ----- |
| Total revenue..... | 37,003 | 27,549 | 22,032 |
| | ----- | ----- | ----- |
| Cost of revenue: | | | |
| Product..... | 14,055 | 11,056 | 10,252 |
| Service..... | 1,225 | 155 | -- |
| | ----- | ----- | ----- |

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

| | | | |
|---|------------|----------|-----------|
| Total cost of revenue..... | 15,280 | 11,211 | 10,252 |
| | ----- | ----- | ----- |
| Gross profit..... | 21,723 | 16,338 | 11,780 |
| | ----- | ----- | ----- |
| Operating expenses: | | | |
| Sales and marketing..... | 11,388 | 7,032 | 6,606 |
| Research and development..... | 2,586 | 3,021 | 2,703 |
| Website and related costs..... | 1,952 | -- | -- |
| General and administrative..... | 5,079 | 3,510 | 2,381 |
| Goodwill amortization..... | 709 | 100 | -- |
| Legal and other related..... | 1,312 | 219 | 826 |
| Impairment charge..... | 1,958 | -- | -- |
| | ----- | ----- | ----- |
| Total operating expenses..... | 24,984 | 13,882 | 12,516 |
| | ----- | ----- | ----- |
| Income (loss) from operations..... | (3,261) | 2,456 | (736) |
| Interest and other income, net..... | 655 | 805 | 663 |
| | ----- | ----- | ----- |
| Income (loss) before taxes..... | (2,606) | 3,261 | (73) |
| Provision for income taxes..... | -- | 129 | -- |
| | ----- | ----- | ----- |
| Net income (loss)..... | \$ (2,606) | \$ 3,132 | \$ (73) |
| | ===== | ===== | ===== |
| Net income (loss) per share: | | | |
| Basic..... | \$ (0.22) | \$ 0.27 | \$ (0.01) |
| | ===== | ===== | ===== |
| Diluted..... | \$ (0.22) | \$ 0.26 | \$ (0.01) |
| | ===== | ===== | ===== |
| Shares used to compute net income (loss) per share: | | | |
| Basic..... | 12,046 | 11,724 | 11,484 |
| | ===== | ===== | ===== |
| Diluted..... | 12,046 | 11,920 | 11,484 |
| | ===== | ===== | ===== |

See accompanying notes to consolidated financial statements.

F-3

54

CHOLESTECH CORPORATION

CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY
(IN THOUSANDS, EXCEPT SHARE DATA)

| | COMMON STOCK | | ACCUMULATED OTHER COMPREHENSIVE | ACCUMULATED |
|--|--------------|----------|---------------------------------------|-------------|
| | SHARES | AMOUNT | INCOME (LOSS) | DEFICIT |
| | ----- | ----- | ----- | ----- |
| Balance at March 27, 1998..... | 11,402,084 | \$69,880 | \$ 49 | \$ (48,483) |
| Net loss..... | -- | -- | -- | (73) |
| Change in unrealized gain on available-for-sale securities..... | -- | -- | (35) | -- |
| Comprehensive loss..... | | | | |
| Issuance of Common Stock pursuant to | | | | |

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

| | | | | |
|--|------------|----------|-------|-------------|
| employee stock purchase plan and exercise of stock options..... | 116,156 | 431 | -- | -- |
| Balance at March 26, 1999..... | 11,518,240 | 70,311 | 14 | (48,556) |
| Net income..... | -- | -- | -- | 3,132 |
| Change in unrealized gain on available-for-sale securities..... | -- | -- | (73) | -- |
| Comprehensive income..... | | | | |
| Issuance of Common Stock pursuant to employee stock purchase plan and exercise of stock options..... | 403,011 | 1,426 | -- | -- |
| Stock compensation expense..... | -- | 132 | -- | -- |
| Warrants issued pursuant to acquisition of Health Net..... | -- | 90 | -- | -- |
| Balance at March 31, 2000..... | 11,921,251 | 71,959 | (59) | (45,424) |
| Net loss..... | -- | -- | -- | (2,606) |
| Change in unrealized gain on available-for-sale securities..... | -- | -- | 128 | -- |
| Comprehensive loss..... | | | | |
| Issuance of Common Stock pursuant to employee stock purchase plan and exercise of stock options..... | 128,386 | 560 | -- | -- |
| Issuance of Common Stock pursuant to Health Net purchase..... | 51,010 | 300 | -- | -- |
| Balance at March 30, 2001..... | 12,100,647 | \$72,819 | \$ 69 | \$ (48,030) |

See accompanying notes to consolidated financial statements.

F-4

55

CHOLESTECH CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(IN THOUSANDS)

| | FISCAL YEAR ENDED | | |
|--|-------------------|-------------------|-------------------|
| | MARCH 30, 2001 | MARCH 31, 2000 | MARCH 26, 1999 |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | | |
| Net income (loss)..... | \$ (2,606) | \$ 3,132 | \$ (73) |
| Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities: | | | |
| Depreciation and amortization..... | 3,471 | 1,597 | 1,112 |
| Change in allowance for doubtful accounts..... | 224 | 269 | 2 |
| Change in inventory reserve..... | 107 | 57 | 152 |
| Change in allowance for sales returns..... | -- | 83 | -- |

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

| | | | |
|---|----------|----------|----------|
| Impairment charge..... | 1,958 | -- | -- |
| Stock compensation expense..... | -- | 132 | -- |
| Changes in assets and liabilities: | | | |
| Accounts receivable..... | (1,394) | 618 | 1,154 |
| Inventories..... | (51) | 816 | (1,378) |
| Prepaid expenses and other assets..... | 188 | (756) | 14 |
| Other assets..... | (21) | -- | 15 |
| Accounts payable and accrued liabilities..... | 85 | 1,944 | (1,570) |
| Accrued payroll and benefits..... | 337 | 573 | (146) |
| Other liability..... | -- | -- | (112) |
| | ----- | ----- | ----- |
| Net cash provided by (used in) operating activities..... | 2,298 | 8,465 | (830) |
| | ----- | ----- | ----- |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | | |
| Restricted cash..... | 1,000 | (1,000) | -- |
| Purchases of marketable securities..... | (11,166) | (26,661) | (19,225) |
| Maturities of marketable securities..... | 9,763 | 25,704 | 22,913 |
| Acquisition of Health Net assets..... | (1,179) | (2,298) | -- |
| Purchase of property and equipment..... | (4,183) | (4,206) | (2,890) |
| | ----- | ----- | ----- |
| Net cash provided by (used in) investing activities... | (5,765) | (8,461) | 798 |
| | ----- | ----- | ----- |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | | |
| Issuance of common stock..... | 560 | 1,426 | 431 |
| | ----- | ----- | ----- |
| Net cash provided by financing activities..... | 560 | 1,426 | 431 |
| | ----- | ----- | ----- |
| Net change in cash and cash equivalents..... | (2,907) | 1,430 | 399 |
| Cash and cash equivalents at beginning of year..... | 6,959 | 5,529 | 5,130 |
| | ----- | ----- | ----- |
| Cash and cash equivalents at end of year..... | \$ 4,052 | \$ 6,959 | \$ 5,529 |
| | ===== | ===== | ===== |
| SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION: | | | |
| Cash paid for income taxes..... | \$ -- | \$ 110 | \$ -- |
| Accrued liability for common stock to be issued for Health Net acquisition..... | -- | 300 | -- |
| Common stock issued for Health Net acquisition..... | 300 | -- | -- |

See accompanying notes to consolidated financial statements.

F-5

56

CHOLESTECH CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. THE COMPANY AND A SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Operations

Cholestech Corporation (the "Company") was incorporated February 2, 1988. Through March 30, 2001 the Company operated in three business segments:

- Diagnostic Products -- which 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 cholesterol-related diseases and to assist in the monitoring of therapy to treat those diseases.

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

- WellCheck(TM) -- which conducts consumer testing within the United States to assess for risk of certain cholesterol-related diseases and to assist in the monitoring of therapy to treat those diseases.
- WellCheck.com -- which provides interactive tools to consumers through the Internet to better assess for risk of certain cholesterol-related diseases and to monitor and motivate personal health management of those diseases.

Beginning in fiscal 2002, the Company will combine WellCheck and WellCheck.com and operate in two business segments.

Summary of significant accounting policies

Fiscal year end

The Company's fiscal year is a 52 - 53 week period ending on the last Friday in March. Fiscal 2001 was comprised of 52 weeks, fiscal 2000 was comprised of 53 weeks, and fiscal 1999 was comprised of 52 weeks.

Principles of consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany transactions and balances have been eliminated.

Revenue recognition

The Company has adopted the provisions of Staff Accounting Bulletin ("SAB") No. 101 "Revenue Recognition in Financial Statements" and believes that its current and historical revenue recognition policy is in compliance with the SAB. The Company has also applied Emerging Issues Task Force Issue No. ("EITF") 00-10 "Accounting for Shipping and Handling Fees and Costs" retroactively to all periods presented. As a result, for all periods presented, amounts billed to customers relating to shipping and handling have been classified as revenue and all related costs are classified as cost of sales.

Revenue from product sales is recognized upon receipt of a purchase order and product shipment provided no significant obligations remain and collection of the receivable is deemed probable.

Revenue associated with testing services is recognized upon completion of the services to be performed under the contract when all obligations are satisfied, and collection of the receivables is deemed probable.

Cash and cash equivalents and marketable securities

The Company considers all highly liquid investments with maturities of three months or less at the date of purchase to be cash equivalents; other investments with maturities of less than one year are classified as short-term marketable securities. The Company has established policies, which limit the type, credit quality and length of maturity of the securities in which it invests. Cash equivalents and marketable securities at March 30, 2001 consist principally of investments in money market funds, commercial paper and U.S. government-agency obligations. Marketable securities are classified as available-for-sale and are carried at

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

their market value at the balance sheet date. Realized gains and losses on sales of all such securities are reported in earnings and computed using the specific identification cost method. Unrealized gains and losses on such securities are included in accumulated comprehensive income/(loss) in shareholders' equity. All investments with maturity dates greater than 365 days are classified as non-current.

There was \$69,000 in unrealized gains as of March 30, 2001 included in the comprehensive income in stockholders' equity and \$59,000 in unrealized losses as of March 31, 2000.

The cost and fair market value of available-for-sale securities at March 30, 2001 are as follows (in thousands):

| | COST | UNREALIZED GAIN | FAIR VALUE | MATURITY DATE |
|----------------------------------|---------|--------------------|------------|-------------------------------|
| | ----- | ----- | ----- | ----- |
| Short-term marketable securities | | | | |
| Commercial paper..... | \$4,675 | \$22 | \$4,697 | April - October 2001 |
| | ===== | === | ===== | |
| Long-term marketable securities | | | | |
| Corporate bonds..... | \$1,034 | \$27 | \$1,061 | May 2002 |
| Government agency..... | 2,535 | 20 | 2,555 | November 2002 - February 2003 |
| | ----- | --- | ----- | |
| | \$3,569 | \$47 | \$3,616 | |
| | ===== | === | ===== | |

The cost and fair market value of available-for-sale securities at March 31, 2000 are as follows (in thousands):

| | COST | UNREALIZED GAIN | FAIR VALUE |
|----------------------------------|---------|--------------------|------------|
| | ----- | ----- | ----- |
| Short-term marketable securities | | | |
| Commercial paper..... | \$1,002 | \$ (4) | \$ 998 |
| Government agency..... | 1,869 | (17) | 1,852 |
| | ----- | --- | ----- |
| | \$2,871 | \$ (21) | \$2,850 |
| | ===== | ==== | ===== |
| Long-term marketable securities | | | |
| Corporate bonds..... | \$3,970 | \$ (38) | \$3,932 |
| | ===== | ==== | ===== |

Restricted cash

There was no restricted cash as of March 30, 2001 as the Health Net acquisition was completed. In fiscal 2000, the Company reported restricted cash of \$1.0 million as part of the Health Net purchase price.

Certain risks and uncertainties

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

Financial instruments that potentially subject the Company to credit risk consist of cash equivalents, marketable securities and accounts receivable. Cash equivalents and marketable securities are maintained with a high credit quality institution, and the composition and maturities of the investments are regularly monitored by management. Generally, these securities are highly liquid and may be redeemed on demand and, therefore, have minimal risk associated with them. The Company has not experienced any material losses on its investments.

The Company's trade accounts receivable generally consist of a large number of small customers. Concentration of credit risk with respect to trade accounts receivable is considered to be limited due to this customer base and the diversity of the Company's geographic sales areas. The Company performs ongoing credit evaluations of its customers' financial condition and, generally, requires no collateral. The Company maintains a provision for potential credit losses and such amounts, in the aggregate, have not been material.

F-7

58

CHOLESTECH CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

Provision is concurrently made for estimated product returns, which historically have been immaterial. In fiscal 2001 one customer accounted for \$6.1 million or 16.4% of total revenue, all of which related to our diagnostic products business compared to fiscal 2000 when two customers accounted for \$2.5 million or 16.9% and \$2.0 million or 11.0% of total revenue, respectively. At March 30, 2001 a single customer accounted for \$876,000 or 32.4% of the total accounts receivable. Two customers accounted for \$218,000 or 11.9% and \$185,000 or 10.1% of total accounts receivable at March 31, 2000.

Inventories

Inventories are stated at the lower of cost or market, cost being determined using the first-in, first-out (FIFO) method. Cost includes direct materials, direct labor and manufacturing overhead.

Property and equipment

Property and equipment are stated at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the related assets, which range from two to five years. Leasehold improvements are amortized over their estimated useful lives, not to exceed the term of the related lease. The cost of additions and improvements is capitalized while maintenance and repairs are charged to expense as incurred. Upon sale or retirement, the asset's cost and related accumulated depreciation are removed from the accounts and any related gain or loss is reflected in operations.

Impairment of long-lived assets

The Company identifies and records impairment losses on long-lived assets when events and circumstances indicate that the future value of such assets 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 their projected discounted future net cash flows.

Goodwill

Goodwill represents the excess of purchase price paid over the value

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

assigned to the net tangible assets of businesses acquired. Goodwill is amortized on a straight-line basis over five years. Periodically, the Company reviews the recoverability of goodwill. The measurement of possible impairment is based primarily on the ability to recover the balance of the goodwill from expected future operating cash flows on an undiscounted basis. Amortization expense was \$709,000 and \$100,000 in fiscal 2001 and 2000, respectively.

A proposed FASB Statement of Financial Accounting Standards on Business Combinations, which would eliminate goodwill amortization, could reduce the total annual amortization expense in periods subsequent to issuance of the final standard.

Website development costs and other internally developed software

The Company accounts for website development costs in accordance with the AICPA Statement of Position ("SOP") 98-1, "Accounting for the Costs of Computer Software Developed or Obtained for Internal Use." The Company has also adopted EITF No. 00-2 "Accounting for the Costs of Developing a Website".

Website development costs consist of external and internal costs incurred to purchase and implement the website software and significant enhancements used in the Company's WellCheck.com business. These costs are capitalized and amortized using the straight-line method over the estimated useful life of the asset, usually three years. In the fourth quarter of fiscal 2001 it was determined that the net book value of the Company's capitalized website costs of \$1.96 million were impaired. Internally developed software consists primarily of

F-8

59

CHOLESTECH CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

Test Event Activity Management System ("TEAMS") software development cost of \$558,000 was capitalized at March 30, 2001.

Internal and external costs of developing website content are expensed as incurred and included in the accompanying consolidated statement of operations in accordance with SOP 98-1.

Research and development

Research and development costs are expensed as incurred.

Warranties

The Company's products are generally under warranty against defects in material and workmanship for a period of up to one year. The Company accrues for estimated future warranty costs at the time of sale. The Company is currently dependent on a sole or limited number of suppliers for certain key components used in its products, which may cause shortages that limit production capacity. There can be no assurance that such shortages will not adversely affect future operating results.

Advertising costs

The cost of advertising is expensed as incurred. Advertising expenses were \$472,000, \$48,000 and \$169,000 for fiscal 2001, 2000 and 1999, respectively.

Income taxes

The Company uses the asset and liability method of accounting for income

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

taxes, which requires the recognition of deferred tax liabilities and assets for the expected future tax consequences of temporary differences between the financial reporting and income tax bases of assets and liabilities.

Net income (loss) per share

Basic earnings per share is computed by dividing net income (loss) (numerator) by the weighted average number of common shares outstanding (denominator) during the period. Diluted earnings per share gives effect to all potential common stock outstanding during a period, if dilutive. The following table reconciles the numerator (net income or loss) and denominator (number of shares) used in the basic and diluted per share computations.

| | NET INCOME (LOSS) | SHARES | PER SHARE |
|------------------------------------|---------------------------------------|--------|-----------|
| | ----- | ----- | ----- |
| | (IN THOUSANDS, EXCEPT PER SHARE DATA) | | |
| Fiscal year ended March 26, 1999: | | | |
| Basic..... | \$ (73) | 11,484 | \$(0.01) |
| Effect of dilutive securities..... | -- | -- | -- |
| Diluted..... | \$ (73) | 11,484 | \$(0.01) |
| Fiscal year ended March 31, 2000: | | | |
| Basic..... | \$ 3,132 | 11,724 | \$ 0.27 |
| Effect of dilutive securities..... | -- | 196 | (0.01) |
| Diluted..... | \$ 3,132 | 11,920 | \$ 0.26 |
| Fiscal year ended March 30, 2001: | | | |
| Basic..... | \$(2,606) | 12,046 | \$(0.22) |
| Effect of dilutive securities..... | -- | -- | -- |
| Diluted..... | \$(2,606) | 12,046 | \$(0.22) |

F-9

60

CHOLESTECH CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

Due to the net loss incurred during fiscal 2001, options to purchase 2,711,304 shares of common stock were considered anti-dilutive at March 30, 2001. At March 31, 2000, options to purchase 1,222,484 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. Due to the net loss incurred during fiscal 1999, options to purchase 1,842,734 shares of common stock were considered anti-dilutive at March 26, 1999.

Fair value of financial instruments

The carrying amounts of certain of our financial instruments including cash and cash equivalents, accounts receivable and accounts payable approximate fair value due to their short maturities.

Use of estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

estimates.

Accounting for stock-based compensation

The Company accounts for stock-based employee compensation arrangements in accordance with provisions of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25") and complies with the disclosure provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123").

Under APB 25, compensation expense for grants to employees is based on the difference, if any, on the date of the grant, between the fair market value of the Company's stock and the option exercise price. SFAS 123 defines a "fair value" based method of accounting for an employee stock option or similar equity investment. The pro forma disclosure of the difference between compensation expense included in net loss and the related cost measured by the fair value method is presented in Note 6.

The Company also adopted FASB Interpretation No. 44, ("FIN 44"), "Accounting for Certain Transactions Involving Stock Compensation -- an Interpretation of APB 25." The adoption of FIN 44 had no material impact on financial reporting and related disclosures of the Company.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS 123 and Emerging Issues Task Force Issue No. 96-18, "Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods and Services," and Financial Accounting Standards Board Interpretation No. 28, "Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plan" ("FIN 28").

Reclassifications

Certain financial statement items have been reclassified to conform to the current year's format. These reclassifications had no impact on previously reported results of operations.

Recent accounting pronouncements

In 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 on the balance sheet and measure those instruments at fair value. The Company, to date, has not

F-10

61

CHOLESTECH CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

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 the first quarter of 2001, the Financial Accounting Standards Board issued an Exposure Draft related to business combinations. If the final results are adopted as proposed, as of January 1, 2002, the Company will no longer be

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

required to amortize goodwill as a charge to earnings. In addition, the Company will be required to periodically review goodwill for potential impairment. If an impairment is found to exist, a charge will be taken against earnings in the Company's consolidated statement of operations. The Company cannot currently determine the amount of an impairment charge, if any, that would be recorded upon adoption.

2. IMPAIRMENT

The Company has been unable to generate significant revenues from website and related databases which during the fourth quarter of fiscal 2001 prompted an impairment review of certain capitalized costs. The Company calculated the present value of expected cash flows for both capitalized website costs and capitalized database costs over the remaining useful lives of these assets to determine the fair value of the assets which provided the basis for measurement of the impairment charge. This review indicated that the assets were fully impaired. Accordingly, in the fourth quarter of fiscal 2001, the Company recorded an impairment charge of \$1.96 million in the WellCheck.com segment.

3. BALANCE SHEET COMPOSITION

Accounts receivable consist of (in thousands):

| | MARCH 30, 2001 | MARCH 31, 2000 |
|---|----------------|----------------|
| | ----- | ----- |
| Accounts receivable..... | \$3,188 | \$2,059 |
| Less allowance for sales returns..... | (83) | (83) |
| Less allowance for doubtful accounts..... | (91) | (137) |
| | ----- | ----- |
| | \$3,014 | \$1,839 |
| | ===== | ===== |

Inventories consist of (in thousands), net:

| | MARCH 30, 2001 | MARCH 31, 2000 |
|-----------------------|----------------|----------------|
| | ----- | ----- |
| Raw materials..... | \$1,263 | \$1,258 |
| Work-in-progress..... | 1,219 | 1,412 |
| Finished goods..... | 1,176 | 1,044 |
| | ----- | ----- |
| | \$3,658 | \$3,714 |
| | ===== | ===== |

F-11

62

CHOLESTECH CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

Property and equipment consist of (in thousands):

| | MARCH 30, 2001 | MARCH 31, 2000 |
|--|----------------|----------------|
|--|----------------|----------------|

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

| | ----- | ----- |
|--|----------|----------|
| Machinery equipment and software..... | \$ 9,447 | \$ 6,927 |
| Furniture and fixtures..... | 371 | 240 |
| Computer equipment..... | 2,528 | 1,734 |
| Leasehold improvements..... | 1,291 | 779 |
| Construction-in-progress..... | 2,745 | 3,694 |
| Website development costs..... | -- | 1,994 |
| | ----- | ----- |
| | 16,382 | 15,368 |
| Less accumulated depreciation and amortization..... | (8,605) | (7,059) |
| | ----- | ----- |
| | \$ 7,777 | \$ 8,309 |
| | ===== | ===== |

Depreciation expense of \$2.8 million was incurred in fiscal 2001, \$1.5 million in fiscal 2000 and \$1.1 million in fiscal 1999. TEAMS software development cost of \$558,000 was capitalized at March 20, 2001 with an accumulated amortization of \$140,000.

Goodwill consists of (in thousands):

| | MARCH 30, 2001 | MARCH 31, 2000 |
|------------------------------------|----------------|----------------|
| | ----- | ----- |
| Cost..... | \$3,952 | \$2,761 |
| Less accumulated amortization..... | (809) | (100) |
| | ----- | ----- |
| | \$3,143 | \$2,661 |
| | ===== | ===== |

Accounts payable and accrued liabilities consist of (in thousands):

| | MARCH 30, 2001 | MARCH 31, 2000 |
|--------------------------------|----------------|----------------|
| | ----- | ----- |
| Trade accounts payable..... | \$1,842 | \$2,823 |
| Accrued legal expenses..... | 1,006 | -- |
| Accrued royalties..... | 155 | 182 |
| Other accrued liabilities..... | 890 | 783 |
| | ----- | ----- |
| | \$3,893 | \$3,788 |
| | ===== | ===== |

4. BORROWING ARRANGEMENTS

In May 2000, the Company entered into a new agreement with its primary bank for an \$8 million revolving line of credit (the "line of credit") replacing its prior agreement for a \$3 million revolving line of credit. While the new line of credit is in effect, the Company is required to maintain on deposit with the bank 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 the bank's prime rate. The line of new credit agreement expires on May 1, 2002. As of March 30, 2001 and

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

March 31, 2000, there were no borrowings outstanding under the lines of credit.

5. COMMITMENTS AND CONTINGENCIES

Leases

We lease office and laboratory facilities under non-cancelable operating leases, which originally expired between March and June 2000. The lease for the Company's approximately 40,000 square foot headquarters facility has been extended and currently expires in March 2002. A second approximately 7,200 square foot facility in Hayward was leased during fiscal 2001 which will expire in October 2003. In November 2000, 5,100

F-12

63

CHOLESTECH CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

square feet of office space in Oakland, California was leased for a five year term. Rent expense was \$609,000, \$374,000 and \$409,000 for fiscal 2001, 2000 and 1999, respectively.

Future minimum payments required under the Company's non-cancelable operating leases at March 30, 2001 were \$688,000, \$258,000, \$216,000, \$192,000 and \$115,000 for fiscal years 2002, 2003, 2004, 2005 and 2006, respectively.

License and development agreements

The Company has obtained rights to use certain technology in manufacturing its products. The related agreement, which expires in 2006, requires the Company to pay a 2.0% royalty on net sales of the applicable products. Total royalty expense for fiscal 2001, 2000 and 1999 was \$490,000, \$456,000 and \$379,000, respectively and was charged to cost of product revenue.

Litigation

On February 5, 1999, a complaint entitled *Ree v. Pinckert, et al.*, No. C99-0562 (PJH) was filed in the United States District Court for the Northern District of California. The action is a putative class action and the Complaint alleges that our company and certain of its current and former officers violated the federal securities laws by making false and misleading statements concerning our Company and its business during the period of June 28, 1996 through June 25, 1998. On June 14, 2001, we executed an agreement in principle with plaintiffs to resolve this matter for a payment \$3 million by our insurance carrier. We recorded a \$1.3 million charge during the fiscal year ended March 30, 2001 for legal fees and insurance costs related to resolving this matter. The settlement is contingent on Court approval.

The Company is subject to various legal claims and assessments in the ordinary course of business, none of which are expected by management to result in a material adverse effect on the consolidated financial statements.

6. SHAREHOLDERS' EQUITY

Preferred stock

The Company is authorized to issue 5,000,000 shares of preferred stock. The board of directors has authority to issue the preferred stock in one or more series and to fix the price, rights preferences, privileges and restrictions thereof, including the dividend rights, dividend rates, conversion rights, voting rights terms of redemption, redemption prices, liquidation preferences,

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

and the number of shares constituting a series or the designation of such series, without any further vote or action by the Company's shareholders. In connection with the Company's shareholder rights plan, 25,000 shares of the preferred stock have been designated Series A participating preferred stock. None of the Shares of Series A participating preferred stock were outstanding as of March 30, 2001, nor was there any activity relating to preferred stock during the three year period ended March 30, 2001.

Stock incentive program

The 1988 Stock Incentive Program (the "1988 Program") provided that incentive stock options ("ISOs") and nonqualified stock options ("NSOs") for shares of common stock could be granted to employees and consultants of the Company. In accordance with the 1988 Program, the exercise price could not be less than 100% and 85% of the fair market value of common stock on the date of the grant for ISOs and NSOs, respectively. The 1988 Program provided that options would be exercisable over a period not to exceed five years and a day. Options vested over four years at a rate of at least 25% each year. Vesting of individual option grants could be accelerated on the occurrence of certain events as described in the stock option

F-13

64

CHOLESTECH CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

agreement. The 1988 Program expired in February 1998. There are no shares available for future grant under the 1988 Program.

In August 1997, the shareholders approved the 1997 Stock Incentive Program (the "1997 Program") which provides ISOs and NSOs for shares of common stock which may be granted to employees and consultants of the Company. In accordance with the 1997 Program, the exercise price may not be less than 100% of the fair market value of common stock on the date of the grant for ISOs and NSOs, respectively. The 1997 Program provides that options shall be exercisable over a period not to exceed seven years and a day. Options vest over four years at a rate of at least 25 percent each year. Vesting of individual option grants may be accelerated on the occurrence of certain events as described in the stock option agreement. There are no shares available for future grant under the 1997 Program.

In August 1999, the board of directors approved the 1999 Nonstatutory Stock Option Plan (the "1999 Program") which provides NSOs for shares of common stock which may be granted to employees and consultants of the Company. In accordance with the 1999 Program, the exercise price may not be less than 100% of the fair market value of common stock on the date of the grant for NSOs. The 1999 Program provides that options shall be exercisable over a period not to exceed 10 years and a day. Options vest over four years at a rate of at least 25% each year. Vesting of individual options grants may be accelerated on the occurrence of certain events as described in the stock option agreement. Pursuant to the terms of the 1999 Program, 1,000,000 shares of common stock are reserved for future issuance.

In August 2000, the shareholders approved the 2000 Stock Incentive Program (the "2000 Program") which provides ISOs and NSOs for shares of common stock which may be granted to employees and consultants of the Company. In accordance with the 2000 Program, the exercise price may not be less than 100% of the fair market value of common stock on the date of the grant for ISOs and NSOs. The 2000 Program provides that options shall be exercisable over a period not to exceed 10 years. Options vest over four years at a rate of at least 25% each year. Vesting of individual option grants may be accelerated on the occurrence

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

of certain events as described in the stock option agreement. Pursuant to the terms of the 2000 Program, 590,000 shares of common stock are reserved for future issuance.

Stock option activity under the programs is as follows:

| | OUTSTANDING OPTIONS | WEIGHTED AVERAGE EXERCISE PRICE PER SHARE |
|------------------------------|------------------------|--|
| | ----- | ----- |
| Balance, March 27, 1998..... | 1,295,665 | \$5.41 |
| Granted..... | 982,386 | 6.73 |
| Exercised..... | (66,804) | 3.39 |
| Canceled..... | (300,151) | 6.47 |
| | ----- | |
| Balance, March 26, 1999..... | 1,911,096 | 5.99 |
| Granted..... | 691,105 | 5.83 |
| Exercised..... | (329,651) | 3.87 |
| Canceled..... | (329,501) | 7.55 |
| | ----- | |
| Balance, March 31, 2000..... | 1,943,049 | 6.03 |
| Granted..... | 1,000,887 | 6.72 |
| Exercised..... | (91,154) | 4.02 |
| Canceled..... | (141,478) | 7.49 |
| | ----- | |
| Balance, March 30, 2001..... | 2,711,304 | 6.28 |
| | ===== | |

As of March 30, 2001, options for 20,056 and 320,988 shares of common stock were available for future grant under the 1999 Program and 2000 Program, respectively.

F-14

65

CHOLESTECH CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

The following table summarizes information about stock options outstanding at March 30, 2001:

| RANGE OF EXERCISE PRICES | OPTIONS OUTSTANDING | | | OPTIONS EXERCISABLE | |
|-----------------------------|---------------------|-----------------------------------|---------------------------------|---------------------|---------------------------------|
| | NUMBER | WEIGHTED AVG. CONTRACTUAL LIFE | WEIGHTED AVG. EXERCISE PRICE | NUMBER | WEIGHTED AVG. EXERCISE PRICE |
| ----- | ----- | ----- | ----- | ----- | ----- |
| \$1.75 - \$ 3.25... | 152,445 | 3.0 | \$2.15 | 73,218 | \$2.13 |
| \$3.26 - \$ 6.56... | 1,530,878 | 4.4 | 5.18 | 1,006,652 | 5.13 |
| \$6.57 - \$14.13... | 1,027,981 | 7.0 | 8.52 | 320,839 | 9.83 |
| | ----- | | | ----- | |
| | 2,711,304 | 6.0 | 6.28 | 1,400,709 | 6.04 |
| | ===== | | | ===== | |

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

Employee stock purchase plan

In April 1992, the Company adopted the Employee Stock Purchase Plan (the "Stock Purchase Plan"), which reserved 75,000 shares of common stock to be issued in accordance with the Internal Revenue Code under such terms as approved by the board of directors. In August 1995, the shareholders approved an increase in the number of shares reserved for issuance under the Stock Purchase Plan from 75,000 to 200,000. In August 1997, the shareholders approved an additional increase in the number of shares reserved for issuance under the Stock Purchase Plan from 200,000 to 400,000. In August 2000, the shareholders approved an additional increase in the number of shares reserved for issuance under the Stock Purchase Plan from 400,000 to 600,000. Under the terms of the Stock Purchase Plan, employees can choose semi-annually to have up to 15% of their compensation withheld to purchase shares of common stock. The purchase price is equal to 85% of the lower of the closing price of the common stock on the NASDAQ National Market on the day the Stock Purchase Plan period begins or ends. Under the Stock Purchase Plan, the Company sold 37,232, 74,188 and 49,352 shares of common stock to employees in fiscal 2001, 2000 and 1999, respectively.

Pro forma disclosures

Had compensation cost for the Company's stock option and stock purchase plans been determined based on the fair market value of the options at the grant dates, as prescribed in SFAS No. 123, the Company's net income (loss) and net income (loss) per share would have been as follows:

| | FISCAL YEAR ENDED | | |
|------------------------------|---------------------------------------|----------------|----------------|
| | MARCH 30, 2001 | MARCH 31, 2000 | MARCH 26, 1999 |
| | (IN THOUSANDS, EXCEPT PER SHARE DATA) | | |
| Net income (loss): | | | |
| As reported..... | \$(2,606) | \$3,132 | \$ (73) |
| Pro forma..... | \$(4,096) | \$2,284 | \$ (871) |
| Net income (loss) per share: | | | |
| As reported -- basic..... | \$ (0.22) | \$ 0.27 | \$(0.01) |
| Pro forma -- basic..... | \$ (0.34) | \$ 0.19 | \$(0.08) |
| As reported -- diluted..... | \$ (0.22) | \$ 0.26 | \$(0.01) |
| Pro forma -- diluted..... | \$ (0.34) | \$ 0.19 | \$(0.08) |

The fair value of each stock option is estimated on the date of the grant using the Black-Scholes valuation model, with the following assumptions used for grants during the applicable periods: dividend yield of 0.0% for all periods; risk free interest rates of 5.9%, 5.7% and 5.3% for options granted during fiscal 2001, 2000 and 1999, respectively; volatility factors of 88%, 93% and 93%, for options granted during fiscal 2001 2000 and 1999, respectively; and a weighted average expected option term of 7.0 years, 6.7 years and 4.0 years for fiscal 2001, 2000 and 1999 respectively. The weighted average per share value of stock options granted in fiscal 2001, 2000 and 1999, was \$5.37, \$4.74 and \$4.20 per share, respectively.

F-15

66

CHOLESTECH CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

The fair value of stock purchase rights is estimated using the

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

Black-Scholes valuation model with the following assumptions for fiscal 2001, 2000 and 1999, respectively; dividend yield of 0.0% for all periods; an expected life of 6 months for all periods; expected volatility factors of 88%, 93% and 93% for fiscal 2001, 2000 and 1999, respectively. The weighted average per share value of stock purchase rights granted in fiscal 2001, 2000, and 1999, was \$1.28, \$0.54 and \$1.12, per share, respectively. The weighted average per share exercise price of stock purchase rights granted in fiscal 2001, 2000 and 1999 was \$5.05, \$2.02 and \$4.16, respectively.

The pro forma effect on net income (loss) and net income (loss) per share for fiscal 2001, 2000 and 1999 is not representative of the pro forma effect on net income (loss) in future periods because it does not take into consideration pro forma compensation expense related to grants made before 1997.

Shareholder rights plan

In January 1997, the board of directors approved a shareholder rights plan under which shareholders of record on March 31, 1997 received a right to purchase (the "Right") one-thousandth of a share of Series A participating preferred stock at an exercise price of \$44.00, subject to adjustment. The Rights will separate from the common stock and Rights certificates will be issued and will become exercisable on the earlier of: (i) 10 days (or such later date as may be determined by a majority of the board of directors) following a public announcement that a person or group of affiliated or associated persons has acquired, or obtained the right to acquire, beneficial ownership of 15% or more of the Company's outstanding common stock or (ii) 10 business days following the commencement of, or announcement of an intention to make, a tender offer or exchange offer, the consummation of which would result in the beneficial ownership by a person or group of 15% or more of the Company's outstanding common stock. The Rights expire on the earlier of (i) January 22, 2007 or (ii) redemption or exchange of the Rights.

7. RETIREMENT SAVINGS PLAN

Effective September 1990, the Company adopted the Cholestech Corporation Retirement Savings Plan (the "401(k) Plan") in which all employees of the Company are entitled to participate. An eligible employee may elect to defer, in the form of contributions to the 401(k) Plan, between 1% and 15% of the employee's W-2 income, not to exceed \$10,500 per year (adjusted for cost-of-living increases). Employee contributions are invested in selected mutual funds or a money market fund as specified by the employee. Employee contributions are fully vested and nonforfeitable at all times. The 401(k) Plan provides for employer contributions as determined by the board of directors. Company contributions to the 401(k) Plan were \$261,000, \$177,000 and \$67,000 in fiscal 2001, 2000 and 1999, respectively.

8. ACQUISITION

On January 21, 2000, the Company completed the purchase of certain assets of Health Net, Inc., a Louisiana corporation ("Health Net"). As consideration the Company paid approximately \$2,499,000 in cash and issued 51,010 shares of its common stock valued at approximately \$300,000. The Purchase Agreement also provided for an additional amount of cash consideration, up to \$1,000,000, to be paid to the former owners of Health Net for achieving certain performance milestones for the calendar year ending December 31, 2000. The actual amount earned and paid to the aforementioned was \$862,000 and was paid on March 29, 2001 from an escrow account. The \$1.0 million was classified as restricted cash on the balance sheet at March 31, 2000. In addition to the Earnout, goodwill of \$330,000 was created during fiscal 2001 from the final purchase audit results and a negotiation resolution.

Health Net marketed and administered medical diagnostic testing services

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

for various venue events, corporations and pharmacies. After the acquisition, Health Net's marketing and administrative functions have been incorporated into WellCheck, the Company's new testing service business which is responsible for ongoing testing programs in retail venues, corporate facilities and other sites convenient to consumers.

F-16

67

CHOLESTECH CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

The acquisition was accounted for using the purchase method of accounting and the results of Health Net have been included in the Company's consolidated financial statements subsequent to January 21, 2000. The allocation of the estimated purchase price to the tangible and intangible assets acquired in connection with this acquisition was based on estimated fair values as determined by management as follows (in thousands):

| | | |
|---|----|-------|
| Total current assets..... | \$ | 285 |
| Property and equipment and other noncurrent assets..... | | 107 |
| Goodwill..... | | 3,952 |
| | | ----- |
| Total purchase price..... | \$ | 4,344 |
| | | ===== |

The following unaudited pro forma information reflects the results of operations as if the Company had acquired Health Net at the beginning of each period presented:

| | FISCAL YEAR ENDED | |
|--|-------------------|----------------|
| | MARCH 31, 2000 | MARCH 26, 1999 |
| (IN THOUSANDS, EXCEPT PER SHARE DATA) (UNAUDITED) | | |
| Revenue: | | |
| As reported..... | \$27,422 | \$22,032 |
| Pro forma..... | \$28,777 | \$22,734 |
| Net income (loss): | | |
| As reported..... | \$ 3,132 | \$ (73) |
| Pro forma..... | \$ 2,848 | \$ (595) |
| Net income (loss) per share: | | |
| As reported -- basic..... | \$ 0.27 | \$ (0.01) |
| Pro forma -- basic..... | \$ 0.24 | \$ (0.05) |
| As reported -- diluted..... | \$ 0.26 | \$ (0.01) |
| Pro forma -- diluted..... | \$ 0.24 | \$ (0.05) |

9. INCOME TAXES

No provision was recorded for the year ended March 30, 2001 as the Company incurred a net operating loss for income tax purposes. A provision for income taxes of \$129,000, all of which is current, was recorded for the year ended March 31, 2000. No provision was recorded for the year ended March 26, 1999 as the Company incurred net operating loss for income tax purposes.

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

The differences between the U.S. federal statutory income tax rate and the Company's effective tax rate for fiscal 2000 are as follows:

| | FISCAL YEAR ENDED MARCH 31, 2000 |
|--|-------------------------------------|
| Provision at statutory rate..... | 34.0% |
| State taxes, net of federal benefit..... | 5.6 |
| Stock options..... | (2.4) |
| Utilization of research and development credits..... | (34.7) |
| Other..... | 1.4 |
| | 3.9% |
| | ===== |

The differences between the U. S. Federal statutory income tax rate and the Company's effective tax rate for fiscal 1999 and 2001 relate primarily to losses for which no benefit was recognized.

F-17

68

CHOLESTECH CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

Deferred tax assets (liabilities) consist of the following (in thousands):

| | MARCH 30, 2001 | MARCH 31, 2000 |
|---|----------------|----------------|
| Net operating loss carryforwards..... | \$ 15,334 | \$ 14,073 |
| Research and development tax credit carryforwards..... | 2,641 | 2,426 |
| Minimum tax credit carryforwards..... | 164 | 186 |
| Capitalized research and development..... | 920 | 756 |
| Other..... | (100) | 416 |
| Valuation allowance for deferred tax assets..... | (18,959) | (17,857) |
| | ----- | ----- |
| | \$ -- | \$ -- |
| | ===== | ===== |

The Company has historically experienced significant operating losses and operates in an industry subject to rapid technological changes. Therefore, management believes that there is sufficient uncertainty regarding the Company's ability to generate future taxable income and utilize its net operating loss and tax credit carryforwards such that a full valuation allowance for deferred tax assets was required at March 30, 2001.

At March 30, 2001 the Company has net operating loss carryforwards available to reduce future taxable income through 2021 for federal tax purposes and through 2006 for state income tax purposes of approximately \$44,259,000 and \$3,240,000, respectively. Additionally, the Company has research and development and other tax credit carryforwards available to reduce income taxes for federal and state income tax purposes of approximately \$1,873,000 and \$768,000, respectively.

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

As a result of a change in ownership which occurred in May 1990, there is an annual limitation of approximately \$1,500,000 for federal and state income tax purposes on the combined use of approximately \$6,131,000 of federal net operating loss carryforwards and the use of approximately \$550,000 of federal and state tax credit carryforwards.

10. SEGMENT INFORMATION

In fiscal 2000, the Company adopted Statement of Financial Accounting Standard ("SFAS") 131, "Disclosures about Segments of an Enterprise and Related Information." During fiscal 2000, the Company launched two new business units, WellCheck and WellCheck.com. As a result, the Company had 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. The accounting policies of the segments are the same as those described in Note 1 -- Summary of Significant Accounting Policies. Segment data includes a charge allocating all corporate-headquarters costs to each of its operating segments and excludes inter-segment revenue. Before 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.

F-18

69

CHOLESTECH CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

Results for fiscal 2001 by segment are as follows (in thousands):

| | DIAGNOSTIC PRODUCTS | WELLCHECK | WELLCHECK.COM | CHOLEST |
|---------------------------------|------------------------|------------|---------------|------------|
| | ----- | ----- | ----- | ----- |
| Net revenue..... | \$32,489 | \$ 4,429 | \$ 85 | \$37,000 |
| Cost of revenue..... | 14,055 | 1,225 | -- | 15,280 |
| | ----- | ----- | ----- | ----- |
| Gross profit..... | 18,434 | 3,204 | 85 | 21,720 |
| | ----- | ----- | ----- | ----- |
| Operating expenses: | | | | |
| Sales and marketing..... | 7,969 | 2,736 | 683 | 11,388 |
| Research and development..... | 2,194 | -- | 392 | 2,586 |
| Website and related costs..... | -- | -- | 1,952 | 1,952 |
| General and administrative..... | 2,647 | 1,143 | 1,289 | 5,079 |
| Goodwill amortization..... | -- | 709 | -- | 709 |
| Legal and other related..... | 438 | 437 | 437 | 1,312 |
| Impairment charge..... | -- | -- | 1,958 | 1,958 |
| | ----- | ----- | ----- | ----- |
| Total operating expenses..... | 13,248 | 5,025 | 6,711 | 24,984 |
| | ----- | ----- | ----- | ----- |
| Operating income (loss)..... | \$ 5,186 | \$ (1,821) | \$ (6,626) | \$ (3,260) |
| | ===== | ===== | ===== | ===== |

The Company has determined that starting in fiscal 2002, WellCheck and WellCheck.com will operate and be managed as one segment. All future operating results will show the combined results for WellCheck and WellCheck.com under a single segment. The wholly owned subsidiary WellCheck.com was legally merged into WellCheck effective June 22, 2001.

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

11. GEOGRAPHIC INFORMATION

The Company's export sales were \$6,460,000, \$4,859,000 and \$2,836,000 for fiscal 2001, 2000 and 1999, respectively. Sales to Europe were \$5,133,000, \$3,960,000 and \$2,069,000 in fiscal 2001, 2000 and 1999, respectively, with the remainder of export sales to the Pacific Rim and Latin America. All of the Company's assets are located in the United States.

F-19

70

SCHEDULE II

CHOLESTECH CORPORATION

VALUATION AND QUALIFYING ACCOUNTS

| | BALANCE AT BEGINNING OF PERIOD | ADDITIONS TO COSTS & EXPENSES | DEDUCTIONS |
|--------------------------------------|--------------------------------------|-------------------------------------|------------|
| | ----- | ----- | ----- |
| FISCAL YEAR ENDED MARCH 26, 1999 | | | |
| Allowance for doubtful accounts..... | \$110,000 | \$ 2,000 | \$ 37,000 |
| Inventory reserve..... | 163,000 | 152,000 | 95,000 |
| FISCAL YEAR ENDED MARCH 31, 2000 | | | |
| Allowance for doubtful accounts..... | \$ 75,000 | \$269,000 | 207,000 |
| Allowance for sales returns..... | -- | 83,000 | -- |
| Inventory reserve..... | 220,000 | 57,000 | 98,000 |
| FISCAL YEAR ENDED MARCH 30, 2001 | | | |
| Allowance for doubtful accounts..... | \$137,000 | \$224,000 | \$270,000 |
| Allowance for sales returns..... | 83,000 | -- | -- |
| Inventory reserve..... | 179,000 | 107,000 | 60,000 |

All other Schedules for which provision is made in the applicable accounting regulations of the Securities and Exchange Commission are not required under the related instructions or are inapplicable, and therefore have been omitted.

F-20

71

EXHIBIT INDEX

| EXHIBIT NUMBER | DESCRIPTION |
|-------------------|--|
| ----- | ----- |
| 3.1(1) | Restated Articles of Incorporation of Registrant |
| 3.2(2) | Bylaws of Registrant, as amended |
| 4.2(3) | Preferred Share Rights Agreement dated January 22, 1997 between Registrant and Chase Mellon Shareholder Services, L.L.C., including the Certificate of Determination, the form of Rights Certificate and Summary of Rights attached thereto as Exhibits A, B and C, respectively |
| 10.1(4) | 1988 Stock Incentive Program and forms of agreements |

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

| | |
|------------|---|
| | thereunder |
| 10.2(5) | 1992 Employee Stock Purchase Plan |
| 10.3(2) | Standard Industrial Lease Agreement between Registrant and Sunlife Assurance Company of Canada dated October 22, 1989 |
| 10.3.1(6) | First Amendment to Standard Industrial Lease Agreement between Registrant and Sunlife Assurance Company of Canada dated April, 1995 |
| 10.4(2) | Forms of Indemnification Agreements between Registrant and its officers and its directors |
| 10.5 | Reserved |
| 10.6 | Reserved |
| 10.6.1 | Reserved |
| 10.7 | Reserved |
| 10.7.1 | Reserved |
| 10.8 | Reserved |
| 10.9 | Reserved |
| 10.10 | Reserved |
| 10.11.1 | Reserved |
| 10.11.2 | Reserved |
| 10.11.3 | Reserved |
| 10.11.4 | Reserved |
| 10.11.5 | Reserved |
| 10.11.6 | Reserved |
| 10.11.7 | Reserved |
| 10.12 | Reserved |
| 10.13 | Reserved |
| 10.14 | Reserved |
| 10.15 | Reserved |
| 10.16 | Reserved |
| 10.17.1(7) | Letter Agreement effective December 20, 1996 by and between Wells Fargo Bank and Registrant |
| 10.17.2(7) | Revolving Line of Credit Note effective December 20, 1996 by and between Wells Fargo Bank and Registrant |
| 10.17.3(7) | General Pledge Agreement effective December 20, 1996 by and between Wells Fargo Bank and Registrant |
| 10.17.4(8) | Revolving Line of Credit Note effective November 30, 1997 by and between Wells Fargo Bank and Registrant |
| 10.17.5(9) | Revolving Line of Credit Note effective November 30, 1998 by and between Wells Fargo Bank and Registrant |

72

| EXHIBIT NUMBER ----- | DESCRIPTION ----- |
|----------------------------|--|
| 10.17.6(10) | Revolving line of Credit Note Effective November 30, 1999 by and between Wells Fargo Bank and Registrant |
| 10.17.7(11) | Revolving line of Credit Note effective May 1, 2000 by and between Wells Fargo Bank and Registrant |
| 10.18 | Reserved |
| 10.19 | Reserved |
| 10.20(12) | 1997 Stock Incentive Program and Form of Agreement thereunder |
| 10.21(13) | 1999 Nonstatutory Stock Option Plan and Form of Agreement thereunder |
| 10.21.1(14) | Distribution Agreement between Registrant and McKesson Drug Company dated August 18, 1998 |
| 10.21.2(14) | Distribution Agreement between Registrant and Bergen Brunswig Corporation dated July 20, 1998 |

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

| | |
|-----------|---|
| 10.22 | Reserved |
| 10.23(15) | Employment Agreement between Registrant and Robert J. Dominici dated July 15, 1998 |
| 10.24(16) | Employment Agreement between Registrant and Jeffrey S. Aroy dated September 3, 1999 |
| 10.25(11) | Employment Agreement between Registrant and Thomas E. Worthy dated August 6, 1999 |
| 10.26(11) | Employment Agreement between Registrant and Terry L. Wassmann dated March 28, 2000 |
| 10.27(11) | Employment Agreement between Registrant and Kevin R. Stromberg dated March 27, 2000 |
| 10.28(11) | Employment Agreement between Registrant and Timothy I. Still dated October 6, 1999 |
| 10.29(17) | 2000 Stock Incentive Program and Form of Agreement thereunder |
| 10.30* | Letter Agreement between Registrant and GMR Marketing, Inc. dated January 23, 2001 |
| 10.31 | Amendment to the Letter Agreement between Registrant and GMR Marketing, Inc. dated April 30, 2001 |
| 10.32 | Employment Agreement between Registrant and William W. Burke dated March 14, 2001 |
| 10.33 | Lease Agreement between Registrant and Terradev Jefferson LLC dated July 28, 2000 |
| 10.34 | Second Amendment to Standard Industrial Lease Agreement between Registrant and Sunlife Assurance Company of Canada dated March 17, 1995 |
| 10.35 | Third Amendment to Standard Industrial Lease Agreement between Registrant and Sunlife Assurance Company of Canada dated January 27, 1997 |
| 10.36 | Fourth Amendment to Standard Industrial Lease Agreement between Registrant and The BIV Group (successor-in-interest to Sunlife Assurance Company of Canada) dated March 3, 2000 |
| 10.3.2 | Reserved |
| 10.3.3 | Reserved |
| 21.1 | Subsidiaries |
| 23.1 | Consent of Independent Accountants |

* Confidential treatment has been requested from the Securities and Exchange Commission with respect to certain portions of this exhibit. The redacted portions have been filed separately with the Securities and Exchange Commission.

- (1) Incorporated by reference to exhibits filed with Registrant's Registration Statement on Form S-1 (No. 33-54300) as declared effective by the Securities and Exchange Commission on December 16, 1992.
- (2) Incorporated by reference to exhibits filed with Registrant's Registration Statement on Form S-1 (No. 33-47603) as declared effective by the Securities and Exchange Commission on June 26, 1992.
- (3) Incorporated by reference to exhibits filed with Registrant's Registration Statement on Form 8-A (No. 000-20198) as declared effective by the Securities and Exchange Commission on March 27, 1997.
- (4) Incorporated by reference to exhibits filed with Registrant's Registration Statement on Form S-8 (No. 333-22475) as declared effective by the Securities and Exchange Commission on February 28, 1997.

73

- (5) Incorporated by reference to exhibits filed with Registrant's Registration

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

Statement on Form S-8 (No. 333-38147) as declared effective by the Securities and Exchange Commission on October 17, 1997, as amended by Registrant's Registration Statement on Form S-8 (No. 333-38147) as declared effective by the Securities and Exchange Commission on October 17, 1997, as amended by Registrant's Registration Statement on Form S-8 (No. 333-44980) as declared effective by the Securities and Exchange Commission on August 31, 2000.

- (6) Incorporated by reference to exhibits filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1995.
- (7) Incorporated by reference to exhibits filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended December 27, 1996.
- (8) Incorporated by reference to exhibits filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended December 26, 1997.
- (9) Incorporated by reference to exhibits filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended December 25, 1998.
- (10) Incorporated by reference to exhibits filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended December 24, 1999.
- (11) Incorporated by reference to exhibits filed with Registrant's Annual Report on Form 10-K for the fiscal year ended March 31, 2000.
- (12) Incorporated by reference to exhibits filed with Registrant's Registration Statement on Form S-8 (No. 333-38151) as declared effective by the Securities and Exchange Commission on October 17, 1997.
- (13) Incorporated by reference to exhibits filed with Registrant's Registration Statement on Form S-8 (No. 333-94503) as declared effective by the Securities and Exchange Commission on January 12, 2000.
- (14) Incorporated by reference to exhibits filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended September 25, 1998.
- (15) Incorporated by reference to exhibits filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended June 25, 1999.
- (16) Incorporated by reference to exhibits filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended September 24, 1999.
- (17) Incorporated by reference to exhibits filed with Registrant's Registration Statement on Form S-8 (333-44980) as declared effective by the Securities and Exchange Commission on August 31, 2000.