

CHOLESTECH CORPORATION

Form 10-K

June 25, 2003

Table of Contents

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K**

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDED MARCH 28, 2003

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)

3347 Investment Boulevard

Hayward, California

(Address of principal executive offices)

94-3065493

(I.R.S. Employer
Identification No.)

94545

(Zip Code)

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

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 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 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.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes No

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 September 27, 2002 as reported on the NASDAQ National Market, was approximately \$114,476,000. Shares of common stock held by each executive officer and director and by each person who owns 5% or more of the outstanding common stock have been excluded from this computation. This determination of affiliate status is not necessarily a conclusive determination for other purposes. The registrant does not have any non-voting stock.

As of May 23, 2003, the registrant had outstanding 13,714,951 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 2003 Annual Meeting of Shareholders to be held August 14, 2003.

TABLE OF CONTENTS

PART I

ITEM 1. BUSINESS

ITEM 2. PROPERTIES

ITEM 3. LEGAL PROCEEDINGS

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

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

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

ITEM 11. EXECUTIVE COMPENSATION

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

ITEM 14. CONTROLS AND PROCEDURES

ITEM 15. PRINCIPAL ACCOUNTANT FEES AND SERVICES

PART IV

ITEM 16. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

SIGNATURES

EXHIBIT INDEX

EXHIBIT 10.40

EXHIBIT 10.40.1

EXHIBIT 10.41

EXHIBIT 10.41.1

EXHIBIT 10.42

EXHIBIT 10.43

EXHIBIT 10.43.1

EXHIBIT 10.44

EXHIBIT 10.45

EXHIBIT 10.46

EXHIBIT 10.46.1

EXHIBIT 10.47

EXHIBIT 10.47.1

EXHIBIT 10.48

EXHIBIT 10.49

EXHIBIT 10.50

EXHIBIT 10.51

EXHIBIT 23.1

EXHIBIT 99.1

Table of Contents

CHOLESTECH CORPORATION

ANNUAL REPORT ON FORM 10-K
For The Fiscal Year Ended March 28, 2003
TABLE OF CONTENTS

PART I		
Item 1.	Business	2
Item 2.	Properties	23
Item 3.	Legal Proceedings	23
Item 4.	Submission of Matters to a Vote of Security Holders	25
PART II		
Item 5.	Market for Registrant's Common Equity and Related Stockholder Matters	25
Item 6.	Selected Consolidated Financial Data	25
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operation	29
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	53
Item 8.	Financial Statements and Supplementary Data	55
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	55
PART III		
Item 10.	Directors and Executive Officers of the Registrant	55
Item 11.	Executive Compensation	55
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	55
Item 13.	Certain Relationships and Related Transactions	55
Item 14.	Controls and Procedures	55
Item 15.	Principal Accountant Fees and Services	56
PART IV		
Item 16.	Exhibits, Financial Statement Schedules and Reports on Form 8-K	56
	Signatures	60

Table of Contents

PART I

Some of the statements contained in this Annual Report on Form 10-K are forward-looking statements about Cholestech Corporation (we, us or Cholestech), including but not limited to those specifically identified as such, that involve risks and uncertainties. The statements contained in the Report on Form 10-K that are not purely historical are forward looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, including, without limitation, statements regarding our expectations, beliefs, intentions or strategies regarding the future. All forward-looking statements included in this Report on Form 10-K are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors, which may cause our actual results to differ materially from those implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as may, will, should, expects, plans, anticipates, believes, estimates, predicts, potential or continue or the negative of these terms or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Moreover, neither any other person nor we assume responsibility for the accuracy and completeness of such statements. Important factors that may cause actual results to differ from expectations include those discussed in Factors Affecting Future Operating Results beginning on page 40 in this document.

We were incorporated under the laws of the State of California in February 1988. Our principal executive offices are located at 3347 Investment Boulevard, Hayward California 94545 and our telephone number at that location is (510) 732-7200. Information about our company is also available at our website at www.cholestech.com, which includes links to reports we have filed with the Securities and Exchange Commission. The contents of our website are not incorporated by reference in this Annual Report on Form 10-K.

ITEM 1. BUSINESS

General

We are a leading provider of diagnostic tools and information for immediate risk assessment and therapeutic monitoring of heart disease and diabetes.

Until December 23, 2002, we engaged in two business activities:

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

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

Table of Contents

On December 23, 2002, we completed the sale (the Sale) of certain assets and the assignment of certain obligations of our wholly owned subsidiary WellCheck Inc. The Sale was made pursuant to the terms and conditions of a Stock Purchase Agreement dated December 23, 2002 (the Agreement) by and among Cholestech, WellCheck and ImpactHealth.com, Inc. (ImpactHealth). Under the terms of the Agreement, we received a secured promissory note in the aggregate principal amount of \$250,000 (the Note) due on the first anniversary of the issuance of the Note, the right to receive an additional \$200,000 contingent upon the attainment of certain performance measures and a royalty per participant tested with TEAMS for three years after the date of the agreement. In addition, we entered into a three-year renewable supply agreement with ImpactHealth involving its purchase of the Cholestech LDX System and single use test cassettes by ImpactHealth on an exclusive basis.

We currently manufacture the LDX System, which includes the LDX Analyzer and a variety of single-use test cassettes, and market the LDX System in the United States, Europe, Asia, Australia and South America. The LDX System, which is waived under the Clinical Laboratory Improvement Amendments (CLIA) allows healthcare providers to perform individual tests or combinations of tests with a single drop of blood from a fingerstick within five minutes. Our current products measure and monitor blood cholesterol, related lipids, glucose and liver function, and are used to test patients at risk of or suffering from heart disease, diabetes and liver disease. The LDX System can also provide the Framingham Risk Assessment from the patient's results as measured on the lipid profile cassette.

We also market and distribute the GDX System under a multi-year global distribution agreement with Provalis Diagnostics Ltd. We began distributing the GDX System under this agreement in July 2002. The Cholestech GDX is a hemoglobin A_{1c} (A1C) testing system that is also waived under CLIA and is used to measure A1C in less than five minutes using a single drop of blood from a fingerstick. The quantitative measure of A1C is well-established as an indicator of a patient's long-term glycemic control. Unlike daily glucose monitoring, which provides a snapshot of a patient's glucose level at the time of testing, A1C provides an average glucose level over the previous 90 days. A1C levels indicate the long-term progress of a patient's diabetes and therapy management.

Market Overview

We believe the market for our products exists where healthcare providers, as well as healthcare product and service organizations, seek to identify, treat and monitor individuals with chronic conditions such as heart disease and diabetes.

High cholesterol is a significant contributing factor to heart disease, which remains the number one cause of death in America and kills 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.

Heart disease is the leading cause of death in people with type 2 diabetes, who die of heart disease at rates two to four times higher than those who do not have diabetes.

Based on the evidence of scientific studies, the National Cholesterol Education Program (NCEP) expert panel and the National Institutes of Health (NIH) issued

Table of Contents

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 significantly reduces the risk of a coronary event by 31%.

According to the NIH guidelines issued in May 2001, approximately 201 million Americans should be screened for high cholesterol. Additionally, the number of Americans on therapeutic lifestyle changes, such as dietary treatment, is expected to increase from about 52 million to about 65 million. The number of Americans prescribed a cholesterol-lowering drug is expected to almost triple from about 13 million to about 36 million.

Diabetes is estimated to afflict approximately 17 million people in the United States, over a third of whom have not yet been identified as being diabetic. Additionally, 33 million Americans require treatment for prevention of diabetes, and 78 million should be screened for diabetes risk according to American Diabetes Association and Health and Human Services guidelines

In 2002, the estimated cost in the United States of coronary heart disease and diabetes was \$210 billion.

The current healthcare system in the United States, while historically successful in treating acute conditions, is currently not adequately serving the growing need for preventive healthcare and the management of chronic disease. In addition, it is estimated that approximately 39 million Americans do not have health insurance. Both of these factors are driving a growing trend towards personal health management, which we believe requires practical, economical and efficient tools to address a widespread, growing need. Our cost effective diagnostic technologies provide convenient, accurate testing as a part of a disease management program and are used for:

screening for heart disease and diabetes by identifying individuals with elevated cholesterol and blood glucose levels; and

monitoring the ongoing condition of people with heart disease and diabetes whose treatment programs may involve long-term, complex drug therapies.

Target Markets

We specifically target our products 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 97,000 sites that are registered with the Centers for Medicare & Medicaid Services (CMS) (formerly the Health Care Finance Administration), approximately 44,000 of which are registered to perform only tests that have been waived under the Clinical Laboratory Improvement Amendments (CLIA waived); and

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.

Table of Contents

Our Strategy

Our strategy is to be the leading provider of diagnostic tools and information for immediate risk assessment and therapeutic monitoring of heart disease and diabetes. The components of this strategy include:

Increase Market Penetration. We intend to further penetrate the physician office laboratory and health promotion markets by increasing the number of installed LDX Analyzers both domestically and internationally through our network of over 70 distributors. We continue to implement marketing and related programs to increase awareness of the advantages of the LDX System among healthcare providers, third party payors and consumers.

Expand Testing Technology. We intend to extend our range of multi-analyte, single-use, disposable cassettes to address additional diagnostic tests to screen for and manage chronic diseases. Our current research and development efforts include the planned introduction of new test cassettes for aspartate aminotransferase and high sensitivity C-reactive protein.

Leverage Our Installed Base. We intend to leverage our installed base of diagnostic systems in each customer location by adding new test cassettes to our current testing platform and offering new products which increase the amount and frequency of testing.

Expand Cassette Usage. We intend to increase the sale of single-use test cassettes through additional placement of LDX Analyzers, development of new diagnostic tests and increased customer relations activities through marketing programs and the deployment of additional field service personnel focused on our installed base.

Expand Manufacturing Capabilities and Efficiencies. We have recently expanded our manufacturing capacity for the manufacture of cassettes. Additionally, we will continue to introduce improvements into our processes designed to enhance our manufacturing operation, including quality, throughput, yields and efficiencies.

Expand Sales Force and Distribution Relationships. We intend to augment our sales and marketing efforts by expanding our sales force as well as our worldwide network of over 70 distributors. By adding resources in our sales and marketing area, we intend to leverage our relationships with distributors by offering additional products.

Products and Products Under Development

We manufacture, market and develop diagnostic testing technology which facilitates the performance of diagnostic testing at alternative sites from traditional hospital laboratories to assist in assessing the risk of heart disease, diabetes and certain liver diseases, and in the monitoring of therapy to treat those diseases. We primarily sell our products through distributors at a discount, based on certain factors, from our published list price. We manufacture and market the LDX System, which is CLIA waived and includes the LDX Analyzer and a variety of single-use test cassettes, in the United States and internationally.

Table of Contents

We also market and distribute the GDX System under a multi-year global distribution agreement with Provalis Diagnostics Ltd. We began distributing the GDX System under this agreement in July 2002. The Cholestech GDX is an A1C testing system that is CLIA waived and is used to measure A1C in less than five minutes using a single drop of blood from a fingerstick. A1C testing monitors the average blood glucose levels of people with diabetes as an indicator of overall blood glucose control. The quantitative measure of A1C is well-established as an indicator of a patient's long-term glycemic control. Unlike daily glucose monitoring, which provides a snapshot of a patient's glucose level at the time of testing, A1C provides an average glucose level over the previous 90 days. A1C levels indicate the long-term progress of a patient's diabetes and therapy management.

Overview of the Cholestech LDX System

The LDX System is an easy to use, multi-analyte testing system consisting of a telephone-sized analyzer, a variety of single-use, credit card-sized test cassettes, a printer and accessories. The LDX System allows healthcare providers to perform individual tests or combinations of tests with a single drop of blood within five minutes. Minimal training is required to operate the LDX System and the sample does not need to be pre-treated. To run a test, the healthcare provider pricks the patient's finger, transfers a drop of blood to the cassette's sample well, inserts the cassette into the LDX Analyzer's cassette drawer and presses the run button. All further steps are performed by the LDX System, which produces results comparable in accuracy to results provided by larger, more expensive bench top and clinical laboratory instruments that are not CLIA waived.

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

The LDX 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. A risk assessment is required by the NIH guidelines.

The LDX Analyzer

The LDX Analyzer is a patented, 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 LDX 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 LDX 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.

Table of Contents

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

Cassette Products

Our line of single-use, disposable test cassettes for the LDX System incorporates patented and licensed technology for distributing precisely measured plasma to up to four 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 LDX Analyzer to convert the reflected color reading into a concentration level for the accurate measurement of the analytes being tested. As a result of this automatic process, the healthcare 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 \$11.25 per cassette and include up to six results per cassette.

Overview of the Cholestech GDX System

The GDX System is a patented, easy to use, A1C testing system consisting of a small desktop analyzer, single-use test cartridges, and accessories. The GDX System allows healthcare providers to perform A1C tests with a single drop of blood within five minutes. Minimal training is required to operate the GDX System and the sample does not need to be pre-treated. To run a test, the healthcare provider pricks the patient's finger, transfers a drop of blood to a sample reagent solution in the test cartridge and initiates a timing sequence. This sample solution and two successive reagent solutions are added to the test cartridge when indicated by the GDX analyzer's user-guiding icon displays. All measurement steps are performed by the GDX System, which produces results comparable in accuracy to results provided by larger, more expensive bench top and clinical laboratory instruments that are not CLIA waived.

The GDX Analyzer

The GDX Analyzer uses a photometer that measures the amount of light transmitted through the reaction solutions and incorporates a microprocessor with built-in software. The GDX Analyzer contains a receptacle for insertion of the cartridge, three buttons for user activation and a liquid crystal display to present user-guiding icons and the test results. The GDX Analyzer's built-in microprocessor regulates the reaction conditions, controls the optical measurements of analyte concentrations in the cartridge's reaction solutions, 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 A1C level and can be

Table of Contents

transferred to a printer, computer or computer network. The GDX Analyzer, along with accessories, comprises a GDX System and currently has a domestic list price of \$895.

Cartridge Product

The GDX System's A1C single-use, disposable test cartridges use a well-established boronate affinity chromatography technique to separate the glycosylated hemoglobin fraction from the nonglycosylated fraction. Hemoglobin in red blood cells becomes glycosylated with prolonged exposure to high levels of glucose (blood sugar) in diabetic patients. After an A1C test cartridge has been placed in the GDX Analyzer, a small sample of blood is added to the first sample solution tube, which contains boronate affinity resin. The red blood cells are instantly disrupted to release the hemoglobin and the boronate affinity resin binds the glycosylated hemoglobin. After a short incubation step, the liquid is poured into the funnel of the test cartridge and the nonglycosylated fraction is collected in an optical chamber where the hemoglobin concentration is photometrically measured. The glycosylated hemoglobin remains bound to the boronate affinity resin, which sits at the bottom of the test cartridge funnel. The boronate affinity resin/glycosylated hemoglobin is then washed with the solution in the second tube. The final step separates the glycosylated hemoglobin from the boronate affinity resin using the solution in the third tube. The glycosylated hemoglobin concentration is then measured and the GDX Analyzer uses an algorithm to convert the results into the percentage A1C in the blood sample. As a result of this automatic process, the healthcare provider does not have to interpret any color reaction, relate a reading to a separate chart or input calibration information. All three tubes used during the test are integral to the test cartridge and the GDX Analyzer displays each step of the process with a user-guiding icon. Our A1C test cartridges currently have a domestic list price of \$7.95 each.

Table of Contents

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

Product	Regulatory Status(1)
Instrument	
LDX Analyzer	FDA cleared; CLIA waived
GDX Analyzer	FDA cleared, CLIA waived
Cassette Products	
<i>Current</i>	
Lipid Profile (Lipid) (Total cholesterol/High density lipoproteins/Calculated low density lipoproteins/Triglycerides)	FDA cleared; CLIA waived
Lipid Profile plus Glucose (Lipid/GLU)	FDA cleared; CLIA waived
Total Cholesterol and Glucose (TC, GLU)	FDA cleared; CLIA waived
Total Cholesterol/High Density Lipoproteins/Glucose (TC, HDL, GLU)	FDA cleared; CLIA waived
Total Cholesterol and High Density Lipoproteins (TC, HDL)	FDA cleared; CLIA waived
Total Cholesterol (TC)	FDA cleared; CLIA waived
Alanine Aminotransferase (ALT)	FDA cleared, CLIA waived
<i>Under Development (2)</i>	
Aspartate Aminotransferase (AST)	Not filed or applied
High Sensitivity C-Reactive Protein (CRP)	Not filed or applied
Lipid Profile/ Alanine Aminotransferase (Lipid/ ALT)	No regulatory filing required
<i>In Feasibility Studies (3)</i>	
Direct Low Density Lipoproteins (LDL)	Not filed or applied
Hemoglobin A _{1c} (A1C)	Not filed or applied
Cartridge Product	
Hemoglobin A _{1c} (A1C)	FDA cleared; CLIA waived

(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 Amendments.

(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 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.

Table of Contents

Current Cassette and Cartridge Products

Our current test products are designed to measure and monitor blood cholesterol, related lipids, glucose, alanine aminotransferase and A1C. Lipids travel in the blood within water-soluble particles called lipoproteins.

Lipid Profile. We offer a lipid profile cassette, which directly measures TC, HDL and triglycerides. This cassette meets all of the screening and monitoring guidelines recommended by the NIH guidelines. 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. NCEP guidelines recommend that healthcare providers perform two lipid profiles, one to four weeks apart, before initiating lipid lowering drug therapy.

Lipid Profile plus Glucose Panel, Total Cholesterol and Glucose Panel, and Total Cholesterol/High Density Lipoproteins/Glucose Panel. Recognizing the relationship between diabetes and abnormal lipid levels, we developed a blood glucose test for the LDX 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 individuals who may be at risk of cardiovascular disease.

Alanine Aminotransferase. Patients undergoing certain drug therapies must be monitored for increases in certain enzymes that are associated with liver damage. The alanine aminotransferase (ALT) test combined with our lipid profile allows healthcare providers to monitor both the impact of and potential adverse side effects on the liver from lipid lowering and diabetic therapies.

Total Cholesterol and High Density Lipoproteins Panel. The Total Cholesterol (TC) and high density lipoproteins (HDL) panel is the recommended test under the current NIH guidelines if the individual being screened has not fasted. 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. This panel also calculates the ratio of TC to HDL, a recognized measure of cholesterol induced cardiac risk.

Total Cholesterol. This stand-alone test for measuring TC was our first test, developed in conjunction with NCEP guidelines issued in 1988.

A1C. Hemoglobin A_{1c} (A1C) is recommended by the American Diabetes Association for long-term management of glycemia in diabetes mellitus. Patients being treated to lower their blood glucose levels are tested from two to four times per year depending on whether their A1C levels are stable or their therapy is changing.

Table of Contents

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 Aminotransferase. Patients undergoing certain drug therapies must be monitored for increases in certain enzymes that are associated with liver damage. The availability of an aspartate aminotransferase (AST) test in conjunction with our ALT test would allow additional healthcare providers to monitor both the impact of and potential adverse side effects on the liver from lipid lowering and diabetic therapies. This cassette product is in the development phase. We expect to receive a 510(k) clearance from the FDA for this product in the fourth quarter of calendar year 2003.

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. Recent research has demonstrated that CRP is a marker of coronary artery inflammation that is an early step in the development of a heart attack. Studies have shown that CRP is an independent risk factor for coronary heart disease and when used in conjunction with certain other risk factors, such as total cholesterol and HDL-cholesterol, is useful in predicting future cardiovascular events. This cassette product is in the development phase. We expect to receive a 510(k) clearance from the FDA for this product by mid-calendar year 2004.

Lipid Profile/Alanine Aminotransferase. We plan to offer a single cassette containing both our CLIA waived lipid profile and ALT tests (Lipid/ALT). The integration of the lipid parameters (total cholesterol, HDL cholesterol and triglycerides) and liver function parameter (ALT) will provide convenience and ease of use for our customers.

Cassette Products in Feasibility Studies

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

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 is reimbursable, whereas the calculated test is not.

Hemoglobin A_{1c}. The American Diabetes Association recommends measurement of A1C for all individuals with diabetes at least twice a year. A1C measurement is a diagnostic test by immunoassay, used by healthcare providers to assess a diabetic's long-term compliance with prescribed diet and insulin usage. A relatively high percentage of A1C to glucose indicates poor patient compliance, which can lead to severe health problems.

Table of Contents

Strategic Relationships

We have established and continually seek to develop strategic relationships to enhance the commercialization of our products. In particular, we intend to enter into additional strategic alliances with major pharmaceutical, health promotion and other companies to enhance our business strategy in chronic diseases and our product offerings. Our current strategic relationships are described below.

Allegiance Healthcare Corporation/Cardinal Health, Inc.

We signed a non-exclusive distribution agreement with Allegiance Healthcare Corporation (*Allegiance*) in November 2001 to market, sell and distribute our products to healthcare providers in the United States, including more than 100,000 physician office laboratories and acute care facilities. We believe our partnership with Allegiance will further our access to medical professionals who seek effective in-office diagnostic and therapeutic monitoring tools for cholesterol and diabetes management. Allegiance is a subsidiary of Cardinal Health, Inc.

Edwards Medical Supply

Edwards Medical Supply (*Edwards*) has been one of our distributors since 1997 and is the nation's leading supplier of medical products and services to the occupational health market. Edwards provides service, product selection and management solutions to occupational health professionals nationwide through over 50 sales representatives and specializes in the coordination and management of large, multi-site medical programs. Edwards also has relationships with national organizations such as the American Association of Occupational Health Nurses (AAOHN), the American College of Occupational and Environmental Medicine (ACOEM) and the American Board for Occupational Health Nurses (ABOHN).

Fisher Scientific International, Inc.

Fisher Scientific International, Inc. (*Fisher*) has been one of our distributors since 1999 and is a supplier of clinical laboratory products, diagnostics and business solutions for the healthcare industry. Fisher markets and distributes these products and services primarily to independent laboratories, hospital laboratories as well as government, university and physicians' office laboratories through a sales network of over 150 sales representatives.

ImpactHealth.com, Inc.

ImpactHealth.com, Inc. (*ImpactHealth*) is a nationwide provider of clinical testing services that markets services and self-testing products to the pharmaceutical, managed care, employer and health product retail industries. In December 2002, ImpactHealth acquired certain assets and obligations of WellCheck. In connection with the acquisition, we have entered into a three-year renewable supply agreement involving the purchase of the LDX System and test cassettes by ImpactHealth on an exclusive basis.

McKesson Corporation

We have a long-term distribution agreement with McKesson Corporation (*McKesson*), a leading healthcare supply management company in North America. Through this agreement, we have access to

Table of Contents

the 500 sales professionals of McKesson's primary care division who call on over 100,000 physician offices and clinics in the United States.

Moore Medical Corp.

We signed a non-exclusive agreement with Moore Medical Corp. (Moore) in December 2001 to market, sell and distribute our products to healthcare providers in the United States, including more than 100,000 occupational health centers, physician office laboratories and acute care facilities.

Physician Sales and Service, Inc.

We entered into a distribution agreement with Physician Sales and Service Inc. (Physician Sales and Service) in 1996 for the distribution of our products to physician offices. Physician Sales and Service has been our largest single customer for the last three years, contributing revenue of \$10.9 million in fiscal 2003, \$8.6 million in fiscal 2002 and \$6.1 million in fiscal 2001.

Provalis Diagnostics Ltd.

In May of 2002, we signed a multi-year agreement with Provalis Diagnostics Ltd. for the global distribution of Provalis Glycosal® (Glycosol) A1C testing and monitoring product which is waived under CLIA. Under the terms of the agreement, we will promote, distribute and sell Glycosal in the United States, the rest of North America, Europe, South America, Australia, Japan and a portion of Asia under the name Cholestech GDx System.

Henry Schein, Inc.

We entered into a distribution agreement with Caligor Medical, which was acquired by Henry Schein, Inc. in 1998. Henry Schein is the largest distributor of healthcare products to office-based practitioners in the combined North American and European markets. Our products are sold through the company's medical business group. Henry Schein reaches its customers through an integrated sales and marketing approach, combining extensive direct marketing programs with more than 700 sales representatives and a network of 1,350 field sales consultants.

Pfizer Inc.

Our LDX System continues to be utilized in a number of regionally based marketing programs in the United States for Pfizer Inc. (Pfizer) in connection with Pfizer's products, as well as field based clinical trials for Lipitor®. Our international sales and marketing team continues to work with Pfizer throughout Europe in connection with physician office and corporate wellness focused marketing programs. Pfizer has renewed its agreement with Impact Health to provide cholesterol testing services at selected healthcare industry conventions in 2003.

Sales and Marketing

Our sales and marketing strategy is to expand our presence in the heart disease and diabetes screening and monitoring markets, focusing primarily on the healthcare professional, pharmaceutical and corporate wellness markets. In order to execute this strategy and create opportunities for our products, we intend to expand our professional sales force and focus our efforts on partnering, distribution and marketing activities.

Table of Contents

Our sales and marketing strategy includes increasing penetration into the physician office laboratory and health promotion markets and leveraging our installed base of LDX and GDX Analyzers. We are expanding the number of domestic sales and field technical service associates. We plan to dedicate a significant portion of the sales and marketing efforts to educate current and potential customers about the clinical and economic benefits of diagnostic screening and therapeutic monitoring 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 base, marketing power and distribution networks of these partners to accelerate market penetration and cassette usage. Our current marketing activities are primarily focused on:

Physician Office Laboratories. We have entered into nonexclusive distribution agreements with five national medical products distributors, Allegiance, Fisher Scientific, McKesson, Physician Sales and Service and Henry Schein, which together have more than 1,700 sales professionals who focus on the United States physician office laboratory market. We have retained more than 35 regional distributors in the United States. In addition, 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.

Health Promotion. We have ongoing relationships with approximately 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 LDX System for the diagnostic screening of employees of Exxon Corporation, General Motors Corporation, Ford Motor Company and Sears, Roebuck and Co. We have also entered into non-exclusive nationwide distribution agreements with Edwards and Moore who specialize in the occupational health arena.

International. Our international distribution strategy is to penetrate targeted geographical markets by selling directly to both high volume users and distributors in those markets. We have entered into non-exclusive agreements with approximately 15 foreign distributors to distribute the LDX System and cassettes primarily in Europe, Asia and South America.

Competition

The diagnostic product markets in which we operate are intensely competitive. Our competition consists primarily of clinical and hospital laboratories, as well as manufacturers of bench top analyzers. The substantial majority of diagnostic tests used by physicians and other healthcare providers are currently performed by clinical and hospital laboratories. We expect that these laboratories will compete aggressively to maintain dominance in the market. To achieve broad market acceptance, we must demonstrate that the LDX System and GDX System are attractive alternatives to bench top 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 LDX System and GDX System will be able to compete with these other analyzers and testing services.

Table of Contents

Companies with a significant presence in the diagnostic products market, such as Abbott Laboratories, Bayer Diagnostics, Beckman Coulter, Inc. and Roche Diagnostics (a subsidiary of Roche Holdings Ltd.), have developed or are developing analyzers designed for point of care testing. 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 LDX System which is waived under CLIA and can provide a complete lipid profile in accordance with the NIH guidelines in less than five minutes using a single drop of blood. In addition, our ALT test, which enables physicians to monitor the potential side effects on the liver from cholesterol lowering drugs and other medications, is the only ALT test waived under CLIA by the FDA. The improving breadth of the CLIA waived tests that we offer our installed base and our network of over 70 distributors. 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 waiver.

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.

Manufacturing

We manufacture, test, perform quality assurance on, package and ship our products from our approximately 76,000 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.

LDX Analyzer. The LDX 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 LDX 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. Our manufacturing process meets FDA Quality System Requirements and ISO 9001 and United Laboratories Guidelines. We believe we can expand our current LDX Analyzer manufacturing capacity as needed.

Cassettes. We purchase chemicals, membranes, plastic parts 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

Table of Contents

membrane impregnation, on-line calibration and software control of the manufacturing process. The overall manufacturing process meets FDA Quality System Requirements and ISO guidelines, including in process and final quality assurance testing. We have two fully operational cassette manufacturing lines and use a third manufacturing line for research and development purposes.

Raw Materials and Quality Assurance. Outside vendors provide us with the subassemblies, components and raw materials necessary for the manufacture of our products. These subassemblies, components and raw materials are inspected and tested by our quality control personnel. We expect the supply of raw materials to be adequate for our current level of business and into the foreseeable future. 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. 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.

Patents and Proprietary Technology

We have nine patents in the United States 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 LDX Analyzer and the method of correcting for the effects of substances that can interfere with testing of a blood sample. We have filed three additional patent applications in the United States and 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) and a portion of 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 three individual European countries. In addition, Roche Diagnostics Corporation and Roche Diagnostics GmbH have filed but not served a suit against us in the United States seeking an injunction and damages for patent infringement. For information concerning this matter, see [Legal Proceedings](#) in this Annual Report on Form 10-K.

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

Table of Contents

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

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 12 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

Table of Contents

510(k) clearance before marketing the LDX 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-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. We were recently inspected by the FDA as part of a routine quality system audit. 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. 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

Table of Contents

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 CMS, register with an 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 healthcare providers to use the LDX System at a lower cost.

Third Party Reimbursement

In the United States, healthcare providers, such as hospitals and physicians that purchase products such as the LDX 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 LDX 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 healthcare providers are moving toward a managed care system in which such providers contract to provide comprehensive healthcare for a fixed cost per patient. Managed care providers are attempting to control the cost of healthcare 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 healthcare costs in the United States in

Table of Contents

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 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 CMS to implement a prospective payment system for outpatient hospital services as well. This system may also provide for a 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 CMS 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 care and services has led to and will continue to lead to increased pressures on the healthcare industry, both foreign and domestic, to reduce the cost of care 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 healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country, and include both government sponsored healthcare 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.

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.

Table of Contents

The services performed by our WellCheck business, prior to its sale in December 2002, entailed risk of professional liability claims. The medical testing industry has historically been litigious, and we may face financial exposure to professional liability, malpractice and cyber liability claims if services provided by our employees and our products resulted in personal injury. There can be no assurance that we will not experience losses due to such claims arising before the sale, in the future. We currently maintain professional liability insurance for the services performed by WellCheck, but there can be no assurance that the coverage limits of our insurance policy will be adequate. Such insurance is expensive 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 continued commercialization of our products. 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 28, 2003, we employed 205 full-time associates. There were 99 employees in manufacturing, 54 employees in sales and marketing, 33 employees in administration and 19 employees in research and development. None of our associates are covered by a collective bargaining agreement, and management considers relations with employees to be excellent.

Executive Officers

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

Name	Age	Position
Warren E. Pinckert II	59	President, Chief Executive Officer and Director
William W. Burke	44	Vice President of Finance, Chief Financial Officer, Treasurer and Secretary
David A. Gyorke	43	Vice President of Engineering
Timothy I. Still	37	Vice President of Sales and Marketing
Terry L. Wassmann	56	Vice President of Human Resources
Donald P. Wood	51	Vice President of Operations
Thomas E. Worthy	61	Vice President of Development and Regulatory Affairs

Warren E. Pinckert II has served as our President, Chief Executive Officer and a Director since June 1993. Mr. Pinckert served as our Executive Vice President of Operations from 1991 to June 1993, and as our Chief Financial Officer and Vice President of Business Development from 1989 to June 1993. Mr. Pinckert also served as our Secretary 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

Table of Contents

PacifiCare Health Systems, Inc., a managed care organization and is on the Board of Advisors for the San Francisco State University School of Business. Mr. Pinckert holds a Bachelor of Science degree in Accounting and a Masters of Business Administration degree from the University of Southern California.

William W. Burke has served as our Corporate Vice President of Finance, Chief Financial Officer, Treasurer and Secretary since March 2001. From August 1998 to March 2001, Mr. Burke was a Managing Director in Bear, Stearns & Co. Inc.'s investment banking department. He was a Managing Director in Everen Securities, Inc.'s investment banking group from May 1991 to May 1995 and January 1998 to August 1998. 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.

David A. Gyorke has served as our Vice President of Engineering since November 2002. From August 2000 to October 2002, Mr. Gyorke served as Vice President of Operations. From January 1999 to August 2000, Mr. Gyorke served as our Director of the Operations Engineering Groups. From November 1993 to 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. Mr. Gyorke has also held positions with Bio-Rad Laboratories, Diasonics Ultrasound Inc., and defense contractors ArgoSystems, Inc. and Raytheon Company. Mr. Gyorke holds a Bachelor of Science degree in Industrial Engineering from the California Polytechnic State University, San Luis Obispo.

Timothy I. Still has served as our Vice President of Marketing and Sales since October 1999. Mr. Still joined Cholestech as the Senior Director of Marketing in December of 1997. Prior to joining Cholestech, Mr. Still was a Director of Global Marketing and Business Development for Boehringer Mannheim Corporation (currently Roche Diagnostics) from August 1992 to November 1997. Before joining Boehringer Mannheim, Mr. Still was a Product Manager with Bio-Rad Laboratories from June 1992 to August 1992. 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.

Terry L. Wassmann has served as our Vice President of Human Resources since March 2000. Before joining Cholestech, Ms. Wassmann served as Staff Relations Manager with Robert Half International from July 1999 to March 2000. From February 1986 to 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. Ms. Wassmann has been awarded the SPHR title from the Society of Human Resource Management.

Donald P. Wood has served as our Vice President of Operations since April 2003. From July 2001 to March 2003, Mr. Wood served as Vice President of Bone Health, a business unit of Quidel Corporation and was responsible for Bone Health Product Operations, Device Research and Development, and Sales and Marketing. He also served as Quidel's Vice President of Ultrasound Operations from August 1999 to July 2001. Prior to joining Quidel, Mr. Wood was the Director of Ultrasound Operations for Metra Biosystems Inc. from July 1998 to August 1999. He also served as its Director of Operations from October 1995 to July 1998. Mr. Wood also served as Senior Director of

Table of Contents

Operations for BioChem Pharma Inc. from July 1994 to October 1995 and held numerous positions within operations for Serono Diagnostics Ltd. from 1980 to July 1994. Mr. Wood holds a Bachelor of Science degree in Business Administration from Bloomsburg University.

Dr. Thomas E. Worthy has served as our Vice President, Development and Regulatory Affairs since August 1999. From April 1998 to August 1999, he served as our Director of Technical Affairs. Before joining Cholestech, Dr. Worthy held Director of Research and Development positions at Microgenics Corporation, a division of Boehringer Mannheim Corporation, from January 1980 to April 1998, 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

Our principal offices are located in a leased 76,000 square foot facility in Hayward, California. Our facilities contain approximately 17,000 square feet of warehouse space, 8,000 square feet of manufacturing space, 4,000 square feet of laboratory space and the balance devoted to marketing and administrative and common areas. Our lease pertaining to this facility expires in April 2007, with an option to extend the lease for an additional three-year term. We expect that our current leased facilities will be sufficient for our needs over the next 12 months.

ITEM 3. LEGAL PROCEEDINGS

On August 2, 2002, N.V. Euromedix (Euromedix) filed suit against us in the Commercial Court in Leuven Belgium (No. F5700-02), seeking damages for the wrongful termination of an implied distribution agreement with our company for Europe and parts of the Middle East. On November 7, 2002, the court dismissed the suit. On December 31, 2002, Euromedix filed suit against us in the Commercial Court in Leuven Belgium (No. F8756-02), seeking damages in the amount of approximately 3.5 million for the wrongful termination of an implied distribution agreement with our company for Europe and parts of the Middle East. A hearing was held on April 29, 2003 regarding certain procedural issues. In a judgment rendered on May 27, 2003, the Court referred the complaint to the Constitutional Court before rendering a final decision. The Court asked the Constitutional Court to render an opinion regarding certain constitutional issues related to the trademark infringement arguments we raised at the hearing. A hearing is scheduled to be held in the Commercial Court on July 8, 2003. We believe these claims are without merit and intend to continue to defend the claims vigorously.

On December 23, 1999, Roche Diagnostics GmbH (Roche) filed suit against us and two of our distributors, Health Care Solutions AG and Euromedix N.V./ SA, in the Canton Court of the Canton Zug in Zug, Switzerland (No. ES580/1999), seeking a cease and desist order barring us from selling HDL assay single-use test cassettes in Switzerland. The complaint alleges that we violated a Roche European patent for HDL. On July 11, 2000, the court denied Roche's request for an injunction and ordered it to pay a portion of our legal fees. On May 2, 2002, in response to our motion, the court ruled that it did not have local jurisdiction over the matter and ordered Roche to pay our legal fees. Roche subsequently appealed the May 2, 2002 decision by the Canton Court of the Canton Zug. On October 7, 2002, the Swiss Federal Tribunal referred the matter back to the Canton Court but rejected the jurisdiction aspect of Roche's appeal. At this point in time, no schedule has been set regarding additional court activity. We believe the claim is without merit and intend to continue to defend the claim vigorously.

Table of Contents

In January 2000, Roche filed suit against us and two of our distributors, Micro-Medical GmbH and Euromedix N.V./SA, in the District Court in Dusseldorf, Germany (No. 4aO4/00), seeking a cease and desist order barring us from selling HDL single-use test cassettes in Germany. The complaint alleges we violated a Roche German priority patent for HDL by selling our single-use test cassette containing a HDL assay in Germany. On December 4, 2001, a hearing was held in Dusseldorf, Germany at which witnesses for Roche and our company testified. On October 29, 2002, the District Court held a hearing on the merits of the case. The court rendered its decision on December 19, 2002, ruling that (i) we are not allowed to further distribute HDL test cassettes which correspond to the German Roche patent, (ii) our distributors must destroy HDL products in their possession, (iii) we and our distributors are subject to unspecified damages based on all sales which occurred in Germany since December 8, 1995 and (iv) we and our distributors must pay the legal fees of the litigation. However, the decision is not enforceable until Roche posts a bond of security in the amount of 2.5 million, approximately \$2.7 million. Roche has not yet posted the bond, nor has it notified the Company of an intention to post the bond. On January 10, 2003, we appealed this ruling with the Appeal Court in Dusseldorf. We believe the claim is without merit and intend to continue to defend the claim vigorously.

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

In September 2000, Roche filed suit against us and one of our distributors in the Commercial Court in Vienna, Austria (No. Ei/Ti ROCH 04002), seeking a cease and desist order barring us from distributing HDL assay single-use test cassettes in Austria. The complaint alleges that we violated a Roche European patent for HDL. On August 9, 2002, the court ruled in our favor and dismissed the patent infringement claim. There can be no assurance as to whether Roche will take any additional action.

On March 3, 2003, Roche Diagnostics Corporation and Roche Diagnostics GmbH filed suit against us in the United States District Court for the Southern District of Indiana (Indianapolis) (No. CV-0303LJM-WTL), seeking a preliminary and permanent injunction, damages and attorneys fees for patent infringement. The plaintiffs have not yet served us with this complaint and we are currently in discussions with the plaintiffs. The complaint alleges that we are violating three Roche U.S. patents for HDL. We believe the claim is without merit and intend to defend the claim vigorously. The defense of this matter is likely to be costly, which could have a material adverse impact on our financial results of operations, and is likely to be time consuming, which could result in substantially diverting the attention of technical and management personnel from our business operations.

Based upon consultation with outside counsel handling our defense in these matters and a discussion of potential results, we do not consider a negative litigation outcome to be probable and have not accrued any amounts for potential losses related to these proceedings. Because of uncertainties related to both the amount and range of loss on the pending litigation, management is unable to make a reasonable estimate of the liability that could result from an unfavorable outcome. As additional information becomes available, we will assess the potential liability related to our pending litigation. We will record accruals for losses if and when we determine the negative outcome of such matters to be probable and reasonably estimable. Our estimates regarding such losses could differ from

Table of Contents

actual results. Revisions in our estimates of the potential liability could materially impact our results of operations and financial position.

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

None.

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 28, 2003, the last reported sale price for our common stock on the NASDAQ National Market was \$8.57 per share. The following table sets forth the quarterly high and low trading prices for our common stock as reported by the NASDAQ National Market for the periods indicated.

	High	Low
FISCAL YEAR 2002		
First Quarter	\$ 8.75	\$ 4.06
Second Quarter	17.90	7.57
Third Quarter	27.60	14.40
Fourth Quarter	22.00	10.82
FISCAL YEAR 2003		
First Quarter	\$20.05	\$ 9.25
Second Quarter	15.30	8.55
Third Quarter	11.45	4.35
Fourth Quarter	8.80	6.00

As of May 23, 2003, there were 13,714,951 shares of our common stock issued and outstanding and held by approximately 167 holders of record. We estimate that there are approximately 5,700 beneficial owners of our common stock.

Dividend Policy

We have never declared or paid cash dividends on our common stock and do not anticipate paying cash dividends in the foreseeable future. We currently expect to retain future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future.

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 28, 2003, March 29, 2002 and March 30, 2001 and the selected consolidated balance sheet data as of March 28, 2003 and March 29, 2002 are derived

Table of Contents

from, and qualified by reference to, the audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. As a result of the sale of our WellCheck business in fiscal 2003, the operations of WellCheck are accounted for as discontinued operation in accordance with Financial Accounting Standards Board Statement No. 144 *Accounting for the Impairment or Disposal of Long-Lived Assets* and Accounting Principles Board Opinion No. 30 *Reporting the Results of Operations - Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions*. Amounts for all periods in this Annual Report on Form 10-K, including the historical statements and related notes, have been reclassified to reflect the presentation of discontinued operations. The selected consolidated statement of operations data for the fiscal years ended March 31, 2000 and March 26, 1999 and the consolidated balance sheet data as of March 30, 2001, March 31, 2000 and March 26, 1999 have been derived from our audited consolidated financial statements not included in this Annual Report. These historical results are not necessarily indicative of the results of operations to be expected from any future period.

In the following discussion of our results of operations, results related to WellCheck have been reclassified as discontinued operations for fiscal year 2003, fiscal 2002, fiscal 2001 and fiscal 2000.

Table of Contents

Year Ended March 31,(1)	2003	2002	2001	2000	1999
<i>(in thousands, except per share data)</i>					
Consolidated Statement of Operations Data:					
Revenue	\$ 48,541	\$ 41,747	\$ 32,489	\$ 26,806	\$ 22,032
Cost of revenue	20,424	17,040	14,054	10,862	10,252
Gross profit	<u>28,117</u>	<u>24,707</u>	<u>18,435</u>	<u>15,944</u>	<u>11,780</u>
Operating expenses:					
Sales and marketing	12,325	10,115	8,287	6,831	6,606
Research and development	2,958	2,564	2,195	2,412	2,703
General and administrative	6,491	5,336	4,293	2,370	2,381
Litigation and other related			1,311	219	826
Total operating expenses	<u>21,774</u>	<u>18,015</u>	<u>16,086</u>	<u>11,832</u>	<u>12,516</u>
Income (loss) from operations	6,343	6,692	2,349	4,112	(736)
Interest and other income, net	438	449	655	805	663
Income (loss) before taxes	6,781	7,141	3,004	4,917	(73)
Provision (benefit) for income taxes(2)	(3,934)	289	224	181	
Income (loss) from continuing operations	<u>10,715</u>	<u>6,852</u>	<u>2,780</u>	<u>4,736</u>	<u>(73)</u>
Loss from discontinued operations	(1,377)	(1,302)	(5,386)	(1,604)	
Loss from sale of discontinued operations	(4,445)				
Net income (loss)	<u>\$ 4,893</u>	<u>\$ 5,550</u>	<u>\$ (2,606)</u>	<u>\$ 3,132</u>	<u>\$ (73)</u>
Income (loss) from continuing operations per share:					
Basic	\$ 0.79	\$ 0.54	\$ 0.23	\$ 0.41	\$ (0.01)
Diluted	\$ 0.76	\$ 0.50	\$ 0.22	\$ 0.40	\$ (0.01)
Loss from discontinued operations per share:					
Basic	\$ (0.43)	\$ (0.10)	\$ (0.45)	\$ (0.14)	\$
Diluted	\$ (0.41)	\$ (0.10)	\$ (0.43)	\$ (0.14)	\$
Net income (loss) per share:					
Basic	\$ 0.36	\$ 0.44	\$ (0.22)	\$ 0.27	\$ (0.01)
Diluted	\$ 0.35	\$ 0.40	\$ (0.21)	\$ 0.26	\$ (0.01)
Shares used to compute net income (loss) per share(3):					
Basic	13,551	12,658	12,046	11,724	11,484
Diluted	14,077	13,730	12,416	11,920	11,484

Table of Contents

Year Ended March 31,(1)	2003	2002	2001	2000	1999
<i>(in thousands)</i>					
Consolidated Balance Sheet Data:					
Cash, cash equivalents, marketable securities and long-term investments	\$ 26,081	\$ 22,107	\$ 12,365	\$ 13,741	\$ 11,427
Working capital	24,679	20,848	10,254	11,522	13,342
Total assets	52,012	42,751	30,742	32,218	24,283
Accumulated deficit	(37,587)	(42,480)	(48,030)	(45,424)	(48,556)
Shareholders' equity	44,728	36,721	24,858	26,476	21,769

(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 28, 2003 as fiscal 2003, March 29, 2002 as fiscal 2002, March 30, 2001 as fiscal 2001, the fiscal year ending March 31, 2000 as fiscal 2000 and the fiscal year ending March 26, 1999 as fiscal 1999.

(2) Benefit for income taxes in fiscal 2003 includes a \$4.2 million gain from a net deferred income tax benefit which resulted from the reversal of a portion of the valuation allowance previously established for our net operating losses.

(3) See Note 1 of Notes to Consolidated Financial Statements for an explanation of the shares used to compute net income (loss) per share.

Table of Contents

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION

Certain statements in this Management's Discussion and Analysis of Financial Condition and Results of Operations are forward looking statements. These statements relate to future events or our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by the forward looking statements. These risks and other factors include those listed under Factors Affecting Future Operating Results 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, 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

We develop, manufacture and market products that perform diagnostic testing at sites outside of traditional hospital and clinical laboratories to assist in assessing for risk of heart disease, diabetes and certain liver diseases and in the monitoring of therapy to treat those diseases. Currently, we manufacture and sell the LDX System, which consists of an analyzer, a test cassette, a printer and accessories, and sell the GDX System, which consists of an analyzer, a test cartridge and accessories.

Until December 2002, our subsidiary WellCheck conducted consumer testing within the United States to help assess the risk of heart disease and other diseases. Using the LDX System and its Test Event Activity Management Software (TEAMS), WellCheck collected test results and other patient data and aggregated that data for testing event sponsors' use in marketing programs.

In December 2002, we completed the sale of certain assets and the assignment of certain obligations of WellCheck to ImpactHealth. We received a secured promissory note in the aggregate principal amount of \$250,000 due on the first anniversary of the issuance of the note, the right to receive an additional \$200,000 contingent upon the attainment of certain performance measures and a royalty per participant tested with TEAMS for three years after the date of the agreement. In addition, we entered into a three-year renewable supply agreement with ImpactHealth involving the purchase of the LDX System and single use test cassettes by ImpactHealth on an exclusive basis.

Today, our revenue is from sales of diagnostic products, test cassettes, test cartridges and related accessories. Although we began marketing and distributing the GDX System in July 2002, we expect that a substantial majority of our revenue will continue to be generated from sales of our LDX product for the foreseeable future.

Table of Contents

Net income in fiscal 2003 included a \$4.2 million gain from an income tax benefit. The net deferred income tax benefit of \$4.2 million results from the reversal of a portion of the valuation allowance previously established for our net operating losses. Based on our recent positive operating results, in the fourth quarter of fiscal 2003, we determined that it was increasingly likely that we would be able to realize a portion of our net operating loss carryforwards in future periods thereby reducing taxes to be paid in those periods.

In connection with our long term growth strategy, we plan to dedicate additional resources in sales and marketing to enhance our market penetration of the physician office laboratory market. We also plan to accelerate our research and development activities in order to introduce new products which can be utilized on our LDX Analyzer. In addition, we are investing a significant amount of capital to improve the efficiency of our manufacturing operations. We also intend to seek opportunities to acquire or distribute single-use test cassettes or other products which can be sold through our established distribution channels.

In addition, legislation to allow Medicare reimbursement for cholesterol, was introduced on February 12, 2003 in both the Senate and House of Representatives, and for diabetes screening, was introduced on March 11, 2003 in the Senate and May 22, 2003 in the House of Representatives. If this legislation is enacted, it may provide further opportunity for us to capitalize on the increasing need for testing in the physician office laboratory market to assess risk for heart disease and diabetes in individuals that we believe could result from passage of such legislation. Further, a major class of cholesterol lowering medications called statins may be approved by the FDA for over the counter sales in the future, which could provide pharmacies with an incentive to conduct testing of patients in the pharmacy as part of a health awareness initiative and provide us with additional opportunities to market our products.

Results of Operations

In the following discussion of our results of operations, results related to WellCheck have been reclassified as discontinued operations for fiscal 2003, fiscal 2002 and fiscal 2001.

Table of Contents

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

Fiscal Year Ended	March 28, 2003	March 29, 2002	March 30, 2001
Revenue	100%	100%	100%
Cost of revenue	42	41	43
Gross profit	58	59	57
Operating expenses			
Sales and marketing	26	24	26
Research and development	6	6	7
General and administrative	13	13	13
Legal and other related			4
Total operating expenses	45	43	50
Income from operations	13	16	7
Interest and other income, net	1	1	2
Provision (benefit) for income taxes	(8)	1	1
Income from continuing operations	22	16	8
Loss from discontinued operations	(3)	(3)	(16)
Loss from sale of discontinued operations	(9)		
Net income (loss)	10%	13%	(8)%

Comparison of Fiscal Years Ended March 28, 2003 and March 29, 2002

Revenue. Our total revenue increased 16% to \$48.5 million in fiscal 2003 from \$41.7 million in fiscal 2002. Domestic revenue represented 86% of total revenue in fiscal 2003 compared to 81% during fiscal 2002. International revenue represented 14% of our total revenue in fiscal 2003 and 19% in fiscal 2002.

The increase in revenue primarily reflected an 11% increase in unit sales of single-use test cassettes. Most of the increase was in the physician office laboratory market where unit sales increased 29%. Additionally, health promotion market unit sales increased 7%. However, unit sales in the international market declined 23% due to reduced promotional activities from large pharmaceutical companies.

LDX System unit sales decreased 5% worldwide in fiscal 2003. The decline was mainly in the health promotion market in which unit sales decreased 10%. International unit sales decreased 21%. However unit sales in the physician office laboratory market increased 29%.

Our new GDX System, which we began selling in July 2002, generated revenue of \$2.4 million. Approximately \$1.7 million of that amount related to single use cartridges, and \$700,000 related to GDX analyzers.

Table of Contents

Cost of Revenue. Cost of revenue includes direct labor, direct material, overhead and royalties. Our cost of revenue increased 20% to \$20.4 million in fiscal 2003 from \$17.0 million in fiscal 2002. Gross margins were 58% in fiscal 2003 and 59% in fiscal 2002. The increase in cost of revenue as a percentage of sales was primarily related to the introduction of the GDX analyzer and test cartridges, which have a lower margin than the products we manufacture. Gross margins for LDX related products were 59% for both fiscal 2003 and fiscal 2002. Manufacturing spending increased 12% to \$14.4 million in fiscal 2003, from \$12.9 million for fiscal 2002. The spending increase was consistent with the 12% increase in production of single-use test cassettes.

We have licensed certain technology used in some of our products. The license agreement, which expires in calendar year 2006, requires us to pay a royalty of 2.0% on net sales of single use test cassettes. Total royalty expense was \$753,000 in fiscal 2003 and \$755,000 in fiscal 2002 and was included in the cost of product revenue.

Operating Expenses

Sales and Marketing. Our sales and marketing expenses include salaries, commissions, bonuses, expenses for outside services related to marketing programs and travel expenses. Sales and marketing expenses increased 22% to \$12.3 million in fiscal 2003 from \$10.1 million in fiscal 2002. Sales and marketing expenses increased to 26% of revenue in fiscal 2003 from 24% of revenue in fiscal 2002. Wages, benefits and other compensation costs increased \$1.1 million, or 29%, to \$5.0 million in fiscal 2003. This increase is attributable to the hiring of 11 additional staff members. Product marketing costs increased \$904,000, or 33%, including sample goods, distributor relations, product design and trade show expense.

Research and Development. Our research and development expenses include salaries, bonuses, expenses for outside services, supplies and amortization of capital equipment. Research and development expenses increased 15% to \$3.0 million in fiscal 2003 from \$2.6 million in fiscal 2002. Research and development expenses as a percentage of revenue remained at 6% in both fiscal 2003 and fiscal 2002. The increase was attributable to consumption of development materials and other related costs which increased \$252,000 due primarily to our efforts to develop a new immunoassay test product. Additionally, wages and other related costs increased \$129,000 due to staffing increases.

General and Administrative. Our general and administrative expenses include salaries and benefits, as well as expenses for outside professional services including information services, legal, accounting, insurance and costs associated with our board of directors. General and administrative expense increased 22% to \$6.5 million in fiscal 2003 from \$5.3 million in fiscal 2002. General and administrative expenses remained at 13% of revenue in both fiscal 2003 and fiscal 2002.

The general and administrative expense increase was attributable to \$591,000 of restructuring costs incurred in December 2002, which included wages, severance and other related costs for two executives and two staff members whose employment was terminated as a result of our management restructuring associated with the divestiture of our WellCheck testing services business. Outside professional services increased \$583,000 and was attributable to an increase in legal costs with respect to European patent litigation and an increase in legal and accounting services relating to Sarbanes-Oxley compliance. Additionally, insurance expense increased \$261,000 relating to an increase in premiums for insurance for our directors and officers.

Table of Contents

Interest and Other Income, Net. Interest income reflects income from the investment of cash balances and marketable securities, net of expenses. Interest income decreased 2% to \$438,000 in fiscal 2003 from \$449,000 in fiscal 2002. This decrease was primarily the result of reduced yields on cash equivalents and marketable securities, together with higher bank service fees.

Income Taxes. Due to our continued profitability, we released \$4.2 million of our tax valuation allowance. This represents our estimated tax benefits to be incurred over the next two fiscal years. We have significant federal net operating loss (NOLs) and tax credit carryforwards. We recorded a \$266,000 tax provision for income taxes in fiscal 2003 and a \$235,000 provision for income taxes in fiscal 2002 which represented the estimated state income 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 2004 and beyond. As of March 28, 2003, we had NOL carryforwards of \$33.9 million available to reduce future taxable income for federal income tax purposes; however, we have fully consumed our NOL carryforwards for California purposes. Additionally, we had research and development and other tax credit carryforwards available to reduce income taxes for federal income tax purposes of \$2.2 million and research and development and other tax credit carryforwards available to reduce income taxes for state income tax purposes of \$109,000.

As a result of a change in ownership (for tax purposes) which occurred in fiscal 1991, 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 net operating loss carryforwards and the use of approximately \$550,000 of federal and state tax credit carryforwards.

Based on our recent positive operating results, in the fourth quarter of fiscal 2003 we determined that it was increasingly likely that we would be able to realize a portion of our net operating loss carryforwards in future periods thereby reducing taxes to be paid in those periods. A valuation allowance of \$4.2 million for deferred tax asset was released for the amount of net operating loss carry forward expected to be utilized in fiscal 2004 and 2005.

Beginning in the first quarter of 2004, we will recognize deferred tax expense for the value of net operating losses utilized. Based on future results, we may recognize additional deferred tax benefits to be realized in these periods.

Discontinued Operations. Discontinued operations include all revenue, cost of revenue, compensation, benefits, travel and expenses for outside professional services including information services and legal expenses related to the operations of WellCheck. Discontinued operations costs increased \$75,000, or 6%, to \$1.4 million for fiscal 2003, from \$1.3 million in fiscal 2002. The primary reason for the increased cost was a smaller number of consumer testing events at which WellCheck provided its testing services, which reduced the amount of billing to sponsors.

Contingent sales proceeds, relating to the terms of the sale of WellCheck, including TEAMS royalty and performance remuneration, will be recognized as earned as a component of discontinued operations.

Loss on Sale of Discontinued Operations. On December 23, 2002, we completed the sale of certain assets and the assignment of certain obligations of our subsidiary WellCheck. We incurred a charge of \$4.4 million reflecting the write-off of certain fixed assets, compensation expenses for staff, professional services, the termination of property leases, and other liabilities in excess of the \$250,000 note receivable.

Table of Contents

Comparison of Fiscal Years Ended March 29, 2002 and March 30, 2001

Revenue. Our total revenue increased 28% to \$41.7 million in fiscal 2002 from \$32.5 million in fiscal 2001. The increase in revenue primarily reflected a 29% increase in unit sales of single-use test cassettes in all of our markets. Additionally, unit sales of the LDX System increased 17%.

Cost of Revenue. Cost of revenue includes direct labor, direct material, overhead and royalties. Our cost of revenue increased 21% to \$17.0 million in fiscal 2002 from \$14.1 million in fiscal 2001. Gross margins were 59% in fiscal 2002 and 57% in fiscal 2001. The increase was primarily related to higher unit sales of single-use test cassettes and our LDX product. The gross margin improvement related to increased production volumes at a rate greater than incremental spending.

We have licensed certain technology used in some of our products. The license 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 \$755,000 in fiscal 2002 and \$490,000 in fiscal 2001 and was included in the cost of product revenue.

Operating Expenses

Sales and Marketing. Our sales and marketing expenses include salaries, commissions, bonuses, expenses for outside services related to marketing programs and travel expenses. Sales and marketing expenses increased 22% to \$10.1 million in fiscal 2002 from \$8.3 million in fiscal 2001. The increase was related to increased wages and other related costs resulting from increased staffing. Sales and marketing expenses decreased to 24% of revenue in fiscal 2002 from 26% of revenue in fiscal 2001.

Research and Development. Our research and development expenses include salaries, bonuses, expenses for outside services, supplies and amortization of capital equipment. Research and development expenses increased 17% to \$2.6 million in fiscal 2002 from \$2.2 million in fiscal 2001. Research and development expenses as a percentage of revenue decreased to 6% in fiscal 2002 compared to 7% in fiscal 2001. This increase was primarily attributable to wage and other costs related to an increase in the number of associates as we began immunoassay test development.

General and Administrative. Our general and administrative expenses include salaries and benefits, as well as expenses for outside professional services including information services, legal, accounting, insurance and costs associated with our board of directors. General and administrative expenses increased 24% to \$5.3 million in fiscal 2002 from \$4.3 million in fiscal 2001. General and administrative expenses remained at 13% of revenue in both fiscal 2002 and fiscal 2001. The increase was related to severance expense for our former chief financial officer, increased wages and other costs related to an increase in the number of associates and higher insurance premiums.

Litigation and Other Related. We recorded no significant litigation and related expenses in fiscal 2002. In fiscal 2001, legal and related expenses included professional consulting fees, court related costs and other fees relating to litigation. Legal and related expenses were \$1.3 million in fiscal 2001. All costs incurred in fiscal 2001 related to a class action lawsuit for which a settlement was reached in June 2001.

Interest and Other Income, Net. Interest income reflects income from the investment of cash balances and marketable securities, net of expenses. Interest income decreased 31% to \$449,000 in fiscal 2002 from \$655,000 in fiscal 2001. This decrease was primarily the result of reduced yields on cash equivalents and marketable securities, together with higher bank service fees.

Table of Contents

Income Taxes. We have significant net operating loss (NOLs) and tax credit carryforwards. The \$235,000 provision for income taxes in fiscal 2002 represented the estimated state income taxes payable, reduced for the use of NOLs and tax credit carryforwards. We recorded no provision for income taxes in fiscal 2001 due to the use of the net operating loss. Management expected to use NOLs and other tax carryforward amounts to the extent taxable income is earned in fiscal 2003 and beyond. As of March 29, 2002, we had NOL carryforwards of \$37.4 million available to reduce future taxable income for federal income tax purposes; however, we had fully consumed our NOL carryforwards for California purposes. Additionally, we had research and development and other tax credit carryforwards available to reduce income taxes for federal income tax purposes of \$2.0 million and research and development and other tax credit carryforwards available to reduce income taxes for state income tax purposes of \$400,000. We have historically experienced significant operating losses and operate in an industry subject to rapid technological changes. Therefore, we believed there was sufficient uncertainty at that time 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 29, 2002.

Discontinued Operations. Discontinued operations include all revenue, cost of revenue, compensation, benefits, travel and expenses for outside professional services including information services and legal related to the operations of WellCheck. In December 2002, we completed the sale of certain assets and the assignment of certain obligations of WellCheck. Discontinued operations costs decreased \$4.1 million, or 76%, to \$1.3 million for fiscal 2002, from \$5.4 million in fiscal 2001. The primary reason for the decrease was a fiscal 2001 impairment charge of \$2.0 million relating to certain capitalized website costs as we no longer expected future cash flows from the website to be sufficient to recover the capitalized development costs. Additionally, we entered into a large, non-renewable contract from a single customer in January 2001, which resulted in a higher revenue and contribution margin than in fiscal 2001.

Liquidity and Capital Resources

We have financed our operations primarily through the sale of equity securities, including employee stock option exercises, and net cash provided by operations. From inception to March 28, 2003, we have raised \$82.2 million in net proceeds from equity financings. As of March 28, 2003, we had \$26.1 million of cash, cash equivalents, marketable securities and long-term investments an increase of \$4.0 million, or 18% from March 29, 2002. 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 either our choice of 0.5% below the bank's prime rate or 1.75% above the LIBOR rate, depending on the payment schedule. The line of credit agreement expires on July 1, 2003. There were no borrowings under this line of credit during fiscal 2003, and as of March 28, 2003, there were no borrowings outstanding under the line of credit.

Net cash provided by operations during fiscal 2003 was \$3.7 million, which was \$2.3 million less than in fiscal 2002. The decline was primarily attributable to a decline in operating income before deferred taxes of \$360,000 and an increase of \$1.6 million in cash used to fund working capital, from \$2.5 million in fiscal 2002 to \$4.1 million in fiscal 2003. Cash used for working capital in 2003 included an increase in accounts receivable of \$1.5 million due to an increase in revenues in the fourth fiscal

Table of Contents

quarter of 2003 compared to the fourth fiscal quarter of 2002, an increase in inventories of \$1.9 million due to investment in inventory for single-use test cassettes and GDx products, and an increase in prepaid expenses and other assets of \$845,000 due primarily to increased directors and officers insurance premiums. This was offset by an increase in accounts payable and accrued liabilities of \$461,000 primarily due to increased inventory purchases.

Additions to plant and equipment were \$2.9 million in fiscal 2003 and \$2.4 million in fiscal 2002. The increase relates mainly to tenant improvements as we expanded our office, warehouse and production space at our Hayward location. Net investments in marketable securities were \$4.0 million, which were \$1.1 million, or 22%, less than fiscal 2002.

Net cash provided by financing activities was \$3.1 million in fiscal 2003 as compared to \$6.2 million for fiscal 2002. 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 2004, we intend to invest approximately \$4.3 million in capital purchases related to expansion of our manufacturing capacity, tenant improvements, and research and development.

Future minimum payments due under lease obligations, including the new lease for our Hayward facility that commenced April 1, 2002, as of March 28 (in thousands):

Fiscal Year	Non Cancelable Operating Leases
2004	\$ 1,022
2005	1,032
2006	1,074
2007	1,115
	—
Total	\$4,243

We expect that cash generated from our projected revenue, existing cash, cash equivalents and marketable securities and proceeds from the exercise of employee stock options will enable us to maintain our current and planned operations for at least the next 12 months. In the event that we would need additional financing for the operation of our business, we can draw upon our existing \$8.0 million line of credit which would require us to maintain cash and investments as collateral. However, we may be required to finance any additional requirements through additional equity, debt financing or credit facilities. We may not be able to obtain additional financings or credit facilities, or if these funds are available, they may not be available on satisfactory terms.

Table of Contents**Quarterly Financial Data**

Quarter Ended	Mar. 28, 2003	Dec. 27, 2002	Sept. 27, 2002	June 28, 2002	Mar. 29, 2002	Dec. 28, 2001	Sept. 28, 2001	June 29, 2001
<i>(In thousands, except share data)</i>								
(unaudited)								
Revenue	\$ 13,480	12,022	\$ 11,906	\$ 11,132	\$ 11,144	\$ 9,988	\$ 10,259	\$ 10,356
Gross profit	7,903	6,453	6,661	7,099	6,693	5,631	6,415	5,969
Income from continuing operations(1)	6,235	790	1,720	1,971	2,201	1,350	1,809	1,493
Loss from discontinued operations	(190)	(4,479)	(596)	(558)	(668)	(196)	(191)	(248)
Net income (loss)	\$ 6,045	\$ (3,689)	\$ 1,124	\$ 1,413	\$ 1,533	\$ 1,154	\$ 1,618	\$ 1,245
Income from continuing operations per share								
Basic	\$ 0.46	\$ 0.06	\$ 0.13	\$ 0.15	\$ 0.17	\$ 0.10	\$ 0.15	\$ 0.12
Diluted	\$ 0.45	\$ 0.06	\$ 0.12	\$ 0.14	\$ 0.15	\$ 0.09	\$ 0.13	\$ 0.12
Income from discontinued operations per share								
Basic	\$ (0.02)	\$ (0.33)	\$ (0.05)	\$ (0.04)	\$ (0.05)	\$ (0.01)	\$ (0.02)	\$ (0.02)
Diluted	\$ (0.01)	\$ (0.33)	\$ (0.04)	\$ (0.04)	\$ (0.04)	\$ (0.01)	\$ (0.01)	\$ (0.02)
Earnings (loss) per share:								
Basic	\$ 0.44	\$ (0.27)	\$ 0.08	\$ 0.11	\$ 0.12	\$ 0.09	\$ 0.13	\$ 0.10
Diluted	\$ 0.44	\$ (0.27)	\$ 0.08	\$ 0.10	\$ 0.11	\$ 0.08	\$ 0.12	\$ 0.10

(1) Income from continuing operations for the quarter ended March 28, 2003 includes a \$4.2 million gain from a net deferred income tax benefit which resulted from the reversal of a portion of the valuation allowance previously established for our net operating losses.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements requires management to make estimates and judgments that affect the reported amounts of assets and liabilities, revenue and expenses and disclosures at the date of the financial statements. On an ongoing basis, we evaluate our estimates, including those related to accounts receivable, inventories and income taxes. We use

Table of Contents

authoritative pronouncements, historical experience and other assumptions as the basis for making estimates. Actual results could differ from these estimates.

We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our consolidated financial statements.

We recognize revenue from product sales when there is pervasive evidence that an arrangement exists, title has transferred to our customers, the price is fixed and determinable and collection is reasonably assured. Provisions for discounts to customers, returns or other adjustments are provided for in the same period that the related product sales are recorded based upon analyses of historical discounts and returns. We recognize revenue associated with services upon completion of the services to be performed under contract when all obligations are satisfied, and collection is reasonably assured. If all conditions to recognize revenue are not met, we are required to defer revenue recognition. In the event that the actual operating environment changes, our operating results for a particular period could be adversely affected.

We maintain an accounts receivable allowance for an estimated amount of losses that may result from a customer's inability to pay for product purchased. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required, which could adversely affect our operating results.

We state inventories at the lower of cost or market. We establish provisions for excess, obsolete and unusable inventories after evaluation of historical sales, forecasted sales, product expiration and current inventory levels. During fiscal 2003, \$92,000 was charged to cost of revenue to increase the provision for excess, obsolete and unusable inventory. If the market value of our products decline, the demand for our products decline or if a significant amount of the material were to become unusable, our operating results could be adversely affected.

Through the end of fiscal 2003, we provided for income taxes based on estimated federal and state alternative minimum taxes payable, reduced for the use of NOLs and tax credit carryforwards. We had historically experienced significant operating losses and operate in an industry subject to rapid technological changes; therefore, we believed there was 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 asset was required at March 29, 2002.

Due to our ongoing profitability from continuing operations over the last eight fiscal quarters, management has elected to release \$4.2 million of our tax valuation allowance. This represents our estimated tax benefits to be incurred over the next two fiscal years. If we continue to remain profitable during the coming fiscal year and determine that realization of all or a portion of the NOLs is likely, then we will further reduce or eliminate the valuation allowance. If the federal or state governments change the corporate income tax laws, our ability to use NOLs and tax credits could be reduced, adversely affecting our operating results.

Table of Contents

We account for stock-based employee compensation arrangements in accordance with provisions of APB Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25) and comply with the disclosure provision of SFAS No. 123, *Accounting for Stock-based Compensation* (SFAS 123) as amended by SFAS No. 148, *Accounting for Stock-based Compensation Transition and Disclosure*. The pro forma disclosure of the difference between compensation expense included in net income (loss) and the related cost measured by the fair value method is presented in Note 1 to the consolidated financial statements included in this Annual Report on Form 10-K. If we were to include the cost of stock-based employee compensation in the financial statements, our operating results would decline based on the fair value of the stock-based employee compensation.

In the first quarter of fiscal 2002, we adopted SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities* (SFAS 133), which establishes accounting and reporting standards for derivative instruments and for hedging activities. We use forward exchange contracts to hedge a portion of certain existing and anticipated foreign currency denominated transactions expected to occur within 12 months. The terms of currency instruments used for hedging purposes are generally consistent with the timing of the transactions being hedged. The purpose of our foreign currency management is to manage the effect of exchange rate fluctuations on certain foreign currency denominated inventory costs and cash flows.

Recent Accounting Pronouncements

In July 2002, the Financial Accounting Standard Board (the FASB) issued Statement of Financial Accounting Standards (SFAS) No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, which supersedes the Emerging Issues Task Force (EITF) Issue No. 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)*. This new standard requires companies to recognize costs associated with exit or disposal activities when the costs are incurred rather than at the date of a commitment to an exit disposal plan. Costs covered by the standard include lease termination costs and certain employee severance costs that are associated with a restructuring, discontinued operation, plant closing, or other exit or disposal activity. This standard is effective for exit or disposal activities that are initiated after December 31, 2002. We adopted this standard and the adoption of this standard had no material impact on our financial statements.

In November 2002, the FASB issued FASB Interpretation No. 45 (FIN 45), *Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*. FIN 45 requires that a liability be recorded in the guarantor s balance sheet upon issuance of a guarantee. In addition, FIN 45 requires disclosures about the guarantees that an entity has issued, including a reconciliation of changes in the entity s product warranty liabilities. The initial recognition and initial measurement provisions of FIN 45 are applicable on a prospective basis to guarantees issued or modified after December 31, 2002, irrespective of the guarantor s fiscal year-end. The disclosure requirements of FIN 45 are effective for financial statements of interim or annual periods ending after December 15, 2002. We adopted this standard and the adoption of this standard had no material impact on our financial statements.

Table of Contents

In November 2002, the EITF reached a consensus on Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* EITF Issue No. 00-21 provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The provisions of EITF Issue No. 00-21 will apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. We believe that the adoption of this standard will have no material impact on our financial statements.

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation, Transition and Disclosure*. SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 also requires that disclosures of the pro forma effect of using the fair value method of accounting for stock-based employee compensation be displayed more prominently and in a tabular format. Additionally, SFAS No. 148 requires disclosure of the pro forma effect in interim financial statements. The transition and annual disclosure requirements of SFAS No. 148 are effective for fiscal years ended after December 15, 2002. The interim disclosure requirements are effective for interim periods beginning after December 15, 2002. We adopted the disclosure requirements of SFAS No. 148.

In January 2003, the FASB issued FASB Interpretation No. 46 (FIN 46), *Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51*. FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective immediately for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period beginning after June 15, 2003. We believe that the adoption of this standard will have no material impact on our financial statements.

Factors Affecting Future Operating Results

We have a history of operating losses and fluctuating operating results, which may result in the market price of our common stock declining

Our revenue and operating results have varied significantly from quarter to quarter in the past and may continue to fluctuate in the future. As of March 28, 2003, we had an accumulated deficit of \$37.6 million. Our first profitable quarter was the third quarter of fiscal 1998, and our first profitable year was fiscal 1998. We recorded a net loss of \$2.6 million for fiscal 2001, a net profit of \$5.6 million for fiscal 2002 and a net profit of \$4.9 million for fiscal 2003. The following are among the factors that could cause our revenue, operating results and margins to fluctuate significantly from quarter to quarter:

- the timing and level of market acceptance of the LDX System and the GDX System;
- variations in manufacturing efficiencies;
- the timing of the introduction, availability and market acceptance of new tests and products;
- the timing and level of expenditures associated with research and development activities;

Table of Contents

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;

additional cost of expanded leased facilities;

promotional program spending by European pharmaceutical companies;

variations in the mix of products sold; and

general economic conditions.

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

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

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

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

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

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

Table of Contents

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

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

We may in the future become subject to patent infringement claims and litigation or interference proceedings conducted in the United States Patent and Trademark Office to determine the priority of inventions. Litigation may also be necessary to enforce any patents issued to us, to protect our trade secrets or know-how or to determine the enforceability, scope and validity of the proprietary rights of others. The defense and prosecution of intellectual property suits, patent interference proceedings and related legal and administrative proceedings are both costly and time consuming and will likely result in substantially diverting the attention of technical and management personnel from our business operations. We may also be subject to significant damages or equitable remedies regarding the development and sale of our products and operation of our business. For information concerning current legal proceedings see **Legal Proceedings** in this Annual Report on Form 10-K.

We rely on trade secrets, technical know-how and continuing invention to develop and maintain our competitive position. Others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technology. We may also be unable to adequately protect our right to our trade secrets.

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

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

quarterly variations in our operating results;

developments in or disputes regarding patent or other proprietary rights;

announcements of technological or competitive developments by us and our competitors;

regulatory developments regarding us or our competitors;

changes in the current structure of the healthcare financing and payment systems;

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.

With the advent of the internet, new avenues have been created for the dissemination of information. We do not have control over the information that is distributed and discussed on electronic bulletin boards and investment chat rooms. The motives of the people or organizations that distribute such information may not be in our best interest or in the interest of our shareholders. This, in addition

Table of Contents

to other forms of investment information, including newsletters and research publications, could result in a sharp decline in the market price of our common stock.

In addition, stock markets have from time to time experienced extreme price and volume fluctuations. The market prices for diagnostic product companies have been affected by these market fluctuations and such effects have often been unrelated to the operating performance of such companies. These broad market fluctuations may cause a decline in the market price of our common stock.

Securities class action litigation is often brought against a company after a period of volatility in the market price of its stock. This type of litigation has been brought against us in the past and could be brought against us in the future, which could result in substantial expense and damage awards and divert management's attention from running our business.

We depend on technology that we license from others, which may not be available to us in the future and would prevent us from introducing new products and harm our business

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

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

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

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

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

healthcare providers are moving toward a managed care system in which they provide comprehensive healthcare for a fixed cost per patient and authorize fewer elective procedures, such as the use of our products for diagnostic screening;

general uncertainty regarding what changes will be made in the reimbursement methods used by third party payors and how that will affect the use of products such

Table of Contents

as ours, which may deter healthcare providers from adopting the use of our products; and

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

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

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

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

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

The market for diagnostic products in which we operate is intensely competitive. Our competition consists primarily of clinical and hospital laboratories, as well as manufacturers of bench top analyzers. To achieve and maintain market acceptance for the LDX System and the GDX System, we must demonstrate that the LDX System and the GDX System are attractive alternatives to bench top analyzers as well as to clinical and hospital laboratories. This will require physicians to change their established means of having such tests performed. The LDX System and the GDX System may be unable to compete with these other testing services and analyzers. In addition, companies with a significant presence in the market for clinical diagnostics, such as Abbott Laboratories, Bayer Diagnostics, Beckman Coulter, Inc. and Roche Diagnostics (a subsidiary of Roche Holdings, Ltd.) have developed or are developing analyzers designed for point of care testing. These competitors have substantially greater financial, technical, research and other resources and larger, more established marketing, sales, distribution and service organizations than us. These competitors also offer broader

Table of Contents

product lines than us, have greater name recognition than us and offer discounts as a competitive tactic. In addition, several smaller companies are currently making or developing products that compete or will compete with ours. We may not have the financial resources, technical expertise or marketing, distribution or support capabilities to compete successfully in the future. Even if we do have such resources and capabilities, we may not employ them successfully.

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

Our LDX System, including the LDX Analyzer and single use test cassettes, currently accounts for substantially all of the revenue of our business. If this revenue does not grow, our overall business will be severely harmed. In addition, we have limited experience marketing and distributing the GDX System, and it is uncertain whether this product will achieve broad market acceptance in our target markets and generate significant revenue in the future. For us to increase revenue, sustain profitability and maintain positive cash flows from operations, the LDX System and the GDX System must continue to and begin to gain market acceptance among healthcare providers, particularly physician office laboratories. We have made only limited sales of the LDX System to physician office laboratories to date relative to the size of the available market. Factors that could prevent broad market acceptance of the LDX System and the GDX System include:

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

the availability and pricing of other testing alternatives;

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

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

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

If our LDX System does not achieve broader market acceptance and our GDX System does not achieve favorable market acceptance, our business will not grow. Even if we are successful in continuing to place our LDX Analyzer at physician office laboratories and other near-patient testing sites and marketing our GDX System, there can be no assurance that placement of these products will result in sustained demand for our single use test cassettes and single use test cartridges.

In addition, we must leverage our installed base of systems in order to increase the sales of our single-use test cassettes and single-use test cartridges. If we are unable to increase the usage of cassettes on our current installed base, we will have to identify new customers and induce them to purchase an analyzer, which requires more time and effort and has a significantly larger purchase price than the single-use test cassettes.

As a result of these many hurdles to achieving broad market acceptance for the LDX System and the GDX System, demand may not be sufficient to sustain revenue and profits from operations. Because

Table of Contents

the LDX System currently contributes the vast majority of our revenue, and we expect the GDX System to contribute a material portion of our revenue in the future, we could be required to cease operations if the LDX System and the GDX System do not achieve and maintain a significant level of market acceptance.

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

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

research and development is a very expensive process;

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

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

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

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

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

new tests must obtain proper regulatory approvals to be marketed.

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

We face risks from failures in our manufacturing processes

We manufacture all of the single use test cassettes that are used with the LDX Analyzer. The manufacture of single use test cassettes is a highly complex and precise process that is sensitive to a wide variety of factors. In the past, we have experienced lower than expected manufacturing yields that have adversely affected gross margins and delayed product shipments. If we do not maintain acceptable manufacturing yields of test cassettes or experience product shipment delays, our business, financial

Table of Contents

condition and operating results could be materially adversely affected. We may reject or be unable to sell a substantial percentage of test cassettes because of:

raw materials variations or impurities;

manufacturing process variances and impurities; and

decreased manufacturing equipment performance.

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

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

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

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

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; and

we have recently completed the process of scaling up a new manufacturing line to production capability. Our failure to maintain production levels and operate this line at production capability for an extended period would impact our ability to increase our manufacturing capacity.

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

We believe we will be required to reduce manufacturing costs for new and existing test cassettes to achieve sustained profitability. We currently operate two manufacturing lines for dry chemistry cassettes. A third manufacturing line is currently used solely for research and development purposes. The complexity and custom nature of our manufacturing process increases the amount of time and money required to add an additional manufacturing line. In addition, we may need to implement additional cassette manufacturing cost reduction programs. Failure to maintain full production levels for our new manufacturing line could prevent us from satisfying customer orders in a timely manner, which could lead to customer dissatisfaction and loss of business and a failure to reduce manufacturing costs for dry chemistry tests, which could prevent us from achieving sustained profitability.

Our future results could be harmed by economic, political, regulatory and other risks associated with international sales

Historically, a significant portion of our total revenue has been generated outside of the United States. International revenue as a percentage of our total revenue was approximately 14% in fiscal 2003

Table of Contents

and 19% in fiscal 2002. We anticipate that international revenue will continue to represent a significant portion of our total revenue in the future. Our revenue is generally denominated in United States dollars; however, a strengthening of the dollar could make our products less competitive in foreign markets and, as a result, our future revenue from international operations may be unpredictable. We make foreign currency denominated purchases related to our GDX System in the United Kingdom. This exposes us to risks associated with currency exchange fluctuations. To minimize this risk, we have undertaken certain foreign currency hedging transactions; however, weakening of the dollar could make the cost of the GDX System less competitive in the domestic market, resulting in less predictable domestic revenue.

In addition to foreign currency risks, our international sales and operations may also be subject to the following risks:

our dependency on pharmaceutical companies promotional programs as a primary source of international revenue;

unexpected changes in regulatory requirements;

the impact of recessions in economies outside the United States;

changes in a specific country s or region s political or economic conditions, particularly in emerging nations;

less effective protection of intellectual property rights in some countries;

changes in tariffs and other trade protection measures;

difficulties in managing international operations; and

potential insolvency of international distributors and difficulty in collecting accounts receivable and longer collection periods.

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

We depend on single source suppliers for certain materials used in our manufacturing process and failure of our suppliers to provide materials to us could harm our business

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

Table of Contents

We depend on distributors to sell our products and failure to maintain and expand these relationships could adversely affect our ability to generate revenue

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 our distributors to assist us in promoting market acceptance of the LDX System and the GDX System. However, we may be unable to enter into and maintain new arrangements on a timely basis, or at all. Even if we do enter into additional distributor relationships, those distributors may not devote the resources necessary to provide effective sales and marketing support to our products. In addition, our distributors sell products offered by our competitors. If our competitors offer our distributors more favorable terms or have more products available to meet their needs, those distributors may de-emphasize or decline to carry our products. If we are unable to maintain successful relationships with distributors or to expand our distribution channels, our business will suffer.

We rely on a limited number of customers for a substantial part of our revenue

Sales to a limited number of customers have accounted for a significant portion of our revenue in each fiscal period. We expect that sales to a limited number of customers will continue to account for a substantial portion of our total revenue in future periods. Our top ten customers comprised 63% of our revenue in fiscal 2003. In fiscal 2003, PSS accounted for approximately 22% of our total revenue and McKesson accounted for 9% of our total revenue. In fiscal 2002, PSS accounted for approximately 20% of our total revenue. We have experienced periods in which sales to some of our major customers, as a percentage of total revenue, have fluctuated due to delays or failures to place expected orders. We do not have long-term agreements with any of our customers, who generally purchase our products pursuant to cancelable short-term purchase orders. If we were to lose a major customer or if orders by or shipments to a major customer were to otherwise decrease or be delayed, our operating results would be harmed.

Our products are subject to multiple levels of government regulation and any regulatory changes are difficult to predict and may be damaging to our business

The manufacture and sale of our diagnostic products, including the LDX System and the GDX System, is subject to extensive regulation by numerous governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies. We are unable to commence marketing or commercial sales in the United States of any of the new tests we develop until we receive the required clearances and approvals. The process of obtaining required regulatory clearances and approvals is lengthy, expensive and uncertain. As a result, our new tests under development, even if successfully developed, may never obtain such clearance or approval. Additionally, certain material changes to products that have already been cleared or approved are subject to further review and clearance or approval. Medical devices are subject to continual review, and later discovery of previously unknown problems with a cleared product may result in restrictions on the product's marketing or withdrawal of the product from the market. If we lose previously obtained clearances, or fail to comply with existing or future regulatory requirements, we may be unable to market the affected products, which would depress our revenue and severely harm our business.

In addition, any future amendment or addition to regulations impacting our products could prevent us from marketing the LDX System and the GDX System. Regulatory changes could hurt our business by increasing burdens on our products or by reducing or eliminating certain competitive advantages of

Table of Contents

the LDX System's and the GDx System's waived status. Food and Drug Administration clearance or approval of products such as ours can be obtained by either of two processes:

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

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

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

The use of our products and those of our competitors is also affected by federal and state regulations, which provide for regulation of laboratory testing, as well as by the laws and regulations of foreign countries. The scope of these regulations includes quality control, proficiency testing, personnel standards and inspections. In the United States, clinical laboratory testing is regulated under the Clinical Laboratory Improvement Act of 1976.

The LDX Analyzer, our total cholesterol, high density lipoproteins, triglycerides and glucose tests in any combination, our ALT test cassette, the GDx Analyzer and A1C test cartridges have been classified as waived from the application of many of the requirements under the CLIA. We believe this waived classification is critical for our products to be successful in their domestic markets. Any failure of our new tests to obtain waived status under the CLIA will severely limit our ability to commercialize such tests. Loss of waived status for existing diagnostic products or failure to obtain waived status for new products could limit our revenue, which would severely harm our business.

We may not be able to use some or all of our deferred tax asset, which may adversely affect our financial results.

During fiscal 2003 we determined, based on eight consecutive quarters of income from continuing operations, it would be prudent to reduce our tax valuation allowance by \$4.2 million reflecting the economic benefits of our enterprise. Changes in existing tax law or adoption of new governmental tax laws or policies could limit, prevent or delay the use of our tax asset. Additionally, changes in the general domestic or world economic condition could result in significant reduction, or elimination of taxable income precluding us from using or eliminating our deferred tax asset.

In addition, United States income tax law imposes limitations on the ability of corporations to use net operating loss carryforwards if the corporation experiences a more than 50% change in ownership during any three-year period. We cannot assure you that we will not take actions, such as the issuance of additional stock, that would cause an ownership change to occur. Accordingly, we may be limited to the amount we can use in any given year, so even if we have substantial net income, we may not be able to use our net operating loss carryforwards before they expire. In addition, the net operating loss carryforwards are subject to examination by the Internal Revenue Service, or IRS, and are thus subject to adjustment or disallowance resulting from any such IRS examination.

If we have taxable income in the future, and we are unable to fully utilize our net operating loss carryforwards, our future tax payments could be higher and our financial results may suffer.

Table of Contents

We may face fines or our manufacturing facilities could be closed if we fail to comply with manufacturing and environmental regulations

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

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

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

other foreign regulations and state and local health, safety and environmental regulations, which include testing, control and documentation requirements.

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

A continuation of the general economic downturn in the United States or abroad may reduce our revenue and harm our business

The primary customers for our products are physician office laboratories and entities conducting health promotion programs. Any significant downturn in domestic or global economic conditions which results in the reduction of the capital spending budgets of our customers or a delay in capital equipment purchases would likely result in a decline in demand for our products and could be detrimental to our business. Economic growth in the United States and other countries has slowed significantly and many commentators believe that the United States economy is experiencing a recession. Overall, customer spending is getting tighter and spending decisions are being more closely scrutinized. These conditions have negatively impacted our business and may continue to do so if they persist.

We may pursue strategic acquisitions which could have an adverse impact on our business if they are unsuccessful

We continue to evaluate strategic opportunities available to us and we may pursue product, technology or business acquisitions. These acquisitions could be very costly, could result in dilution to existing investors and could result in integration problems that harm our business as a whole. Any acquisition could result in expending significant amounts of cash, issuing potentially dilutive equity securities or incurring debt or unknown liabilities associated with the acquired business. In addition, our acquisitions may not be successful in achieving our desired strategic objectives, which could materially harm our operating results and business. Acquisitions may also result in difficulties in assimilating the operations, technologies, products, services and personnel of the acquired company or business or in

Table of Contents

achieving the cost savings or other financial benefits we anticipated. These difficulties could result in additional expenses, diversion of management attention and an inability to respond quickly to market issues. Any of these results could harm us financially.

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

If we are successful in achieving and maintaining market acceptance for the LDX System and the GDX 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.

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

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

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

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

We currently maintain product liability insurance and professional liability insurance for claims relating to the past performance of testing services, but there can be no assurance that the coverage limits of our insurance policies will be adequate. Insurance is expensive and difficult to obtain, and we may be unable to maintain product liability insurance in the future on acceptable terms or in sufficient amounts to protect us against losses due to product liability. Inability to maintain insurance at an

Table of Contents

acceptable cost or to otherwise protect against potential product liability could prevent or inhibit the continued commercialization of our products. In addition, a product liability or professional liability claim in excess of relevant insurance coverage or a product recall could severely hurt our financial condition.

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

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

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

We have made use of a device 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 antitakeover 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.

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.

Table of Contents

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

We have concluded that the fair market value of our investment portfolio or related income would not be significantly impacted by short term changes in interest rates due to the nature of our marketable securities, which have maturity dates that do not exceed fiscal 2007 and have primarily fixed interest rates.

We enter into forward exchange contracts to manage foreign currency exposures arising from inventory purchases and accounts payable denominated in foreign currencies. Our policy is to hedge 100% of all committed purchase contracts and a lesser percentage for forecasted purchases. At March 28, 2003, we had outstanding forward contracts to purchase £1.6 million for approximately \$2.6 million. The open contracts mature at various dates through December 18, 2003 and hedge certain forecasted inventory purchases denominated in the British Pound Sterling. The unrealized loss on the forward contracts at March 28, 2003 was \$24,000, all of which is expected to be reclassified to earnings within the next 12 months. There was no gain or loss recorded in the period from hedge ineffectiveness or from forecasted transactions no longer expected to occur. We do not enter into foreign exchange forward contracts for trading purposes. We do not expect gains or losses on these contracts to have a material impact on our financial results.

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

Fiscal Year	2004	2005	2006	2007	Total	Fair Value
<i>(in thousands)</i>						
Cash, cash equivalents	\$8,747	\$	\$	\$	\$ 8,747	\$ 8,747
Short-term marketable securities	\$4,776	\$	\$	\$	\$ 4,776	\$ 4,776
Weighted average interest rate	1.81%					
Long-term marketable securities	\$	\$7,299	\$3,256	\$2,003	\$12,558	\$12,558
Weighted average interest rate	4.24% 4.28% 2.33%					

Qualitative Disclosures

Our primary interest rate risk exposures relate to:

available for sale securities will fall in value if market interest rates increase; and

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.

Table of Contents

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our consolidated financial statements and the independent accountants' report appear on pages F-1 to F-25 of this Annual Report. See Item 16 for an index of consolidated financial statements and supplementary data.

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

Not applicable.

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 2003 Annual Meeting of Shareholders to be held August 14, 2003, 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 is set forth in Part I of this Annual Report under "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.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference from the section captioned "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" 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 "Related Party Transactions" contained in the Proxy Statement.

ITEM 14. CONTROLS AND PROCEDURES

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure based closely on the definition of

Table of Contents

disclosure controls and procedures in Rule 13a-14(c). In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Within 90 days prior to the date of this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective.

There have been no significant changes in our internal controls or in other factors that could significantly affect the internal controls subsequent to the date we completed our evaluation.

ITEM 15. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference from the section captioned Proposal Two Ratification of Appointment of Independent Accountants in the Proxy Statement.

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

PART IV

ITEM 16. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

(a)(1) *Financial Statements.*

The following consolidated financial statements are included in this Annual Report on Form 10-K:

	Page
Report of Independent Accountants	F-1
Consolidated Balance Sheets at March 28, 2003 and March 29, 2002	F-2
Consolidated Statements of Operations for the years ended March 28, 2003, March 29, 2002 and March 30, 2001	F-3
Consolidated Statement of Changes in Shareholders' Equity for the years ended March 28, 2003, March 29, 2002 and March 30, 2001	F-4
Consolidated Statements of Cash Flows for the years ended March 28, 2003, March 29, 2002 and March 30, 2001	F-5
Notes to Consolidated Financial Statements	F-6
(a)(2) <i>Financial Statement Schedules.</i>	
Schedule II Valuation and Qualifying Accounts	F-26

Table of Contents

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

(a)(3) *Exhibits.*

3.1(1)	Restated Articles of Incorporation of Registrant
3.2(2)	Bylaws of Registrant, as amended to date
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, as amended, and forms of agreements thereto
10.3(2)	Standard Industrial Lease Agreement between Registrant and Sunlife Assurance Company of Canada dated October 22, 1989
10.3.1(5)	First Amendment to Standard Industrial Lease Agreement between Registrant and Sunlife Assurance Company of Canada dated April 1995
10.4(2)	Form of Indemnification Agreement between Registrant and its officers and its directors
10.17.1(6)	Letter Agreement effective December 20, 1996 by and between Wells Fargo Bank and Registrant
10.17.2(6)	Revolving Line of Credit Note effective December 20, 1996 by and between Wells Fargo Bank and Registrant
10.17.3(6)	General Pledge Agreement effective December 20, 1996 by and between Wells Fargo Bank and Registrant
10.17.4(7)	Revolving Line of Credit Note effective November 30, 1997 by and between Wells Fargo Bank and Registrant
10.17.5(8)	Revolving Line of Credit Note effective November 30, 1998 by and between Wells Fargo Bank and Registrant
10.17.6(9)	Revolving Line of Credit Note Effective November 30, 1999 by and between Wells Fargo Bank and Registrant
10.17.7(10)	Revolving Line of Credit Note effective May 1, 2000 by and between Wells Fargo Bank and Registrant
10.17.8(11)	Revolving Line of Credit Note effective September 10, 2001 by and between Wells Fargo Bank and Registrant
10.20(12)	1997 Stock Incentive Program, as amended, and form of agreement thereto
10.21(13)	1999 Nonstatutory Stock Option Plan, as amended, and form of agreement thereto
10.24(17)	Employment Agreement between Registrant and David A. Gyorke dated July 6, 2000
10.25(10)	Employment Agreement between Registrant and Thomas E. Worthy dated August 6, 1999
10.26(10)	Employment Agreement between Registrant and Terry L. Wassmann dated March 28, 2000
10.28(10)	Employment Agreement between Registrant and Timothy I. Still dated October 6, 1999
10.29(11)	2000 Stock Incentive Program, as amended, and form of agreement thereto
10.32(14)	Employment Agreement between Registrant and William W. Burke dated March 14, 2001
10.33(14)	Lease Agreement between Registrant and Terradev Jefferson LLC dated July 28, 2000
10.34(14)	Second Amendment to Standard Industrial Lease Agreement between Registrant and Sunlife Assurance Company of Canada dated March 17, 1995

Table of Contents

10.35(14)	Third Amendment to Standard Industrial Lease Agreement between Registrant and Sunlife Assurance Company of Canada dated January 27, 1997
10.36(14)	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
10.37(11)	Lease Agreement between Registrant and the BIV Group dated July 23, 2001
10.38(15)	2002 Employee Stock Purchase Plan and form of agreement thereto
10.39(16)	Stock Purchase Agreement dated December 23, 2002 between Registrant, WellCheck Inc. and ImpactHealth.com, Inc.
10.40	Amended and Restated Severance Arrangement between Registrant and Warren E. Pinckert II dated June 14, 2001
10.40.1	First Amendment to Amended and Restated Severance Arrangement between Registrant and Warren E. Pinckert II dated March 27, 2003
10.41	Change of Control Severance Agreement between Registrant and Warren E. Pinckert II dated June 14, 2001
10.41.1	First Amendment to Change of Control Severance Agreement between Registrant and Warren E. Pinckert II dated January 23, 2003
10.42	Severance Agreement between Registrant and William W. Burke dated July 17, 2001
10.43	Change of Control Severance Agreement between Registrant and William W. Burke dated July 21, 2001
10.43.1	First Amendment to Change of Control Severance Agreement between Registrant and William W. Burke dated January 23, 2003
10.44	Severance Agreement between Registrant and David A. Gyorke dated July 25, 2001
10.45	Severance Agreement between Registrant and Timothy I. Still dated July 19, 2001
10.46	Severance Agreement between Registrant and Terry L. Wassmann dated July 17, 2001
10.46.1	First Amendment to Severance Agreement between Registrant and Terry L. Wassmann dated January 23, 2003
10.47	Change of Control Severance Agreement between Registrant and Terry L. Wassmann dated January 23, 2003
10.47.1	First Amendment to Change of Control Severance Agreement between Registrant and Terry L. Wassmann dated January 23, 2003
10.48	Severance Agreement between Registrant and Thomas E. Worthy dated July 19, 2001
10.49	Transition Agreement between Registrant and Robert J. Dominici dated December 18, 2002
10.50	Employment Agreement between Registrant and Donald P. Wood dated March 31, 2003
10.51	Severance Agreement between Registrant and Donald P. Wood dated April 1, 2003
23.1	Consent of Independent Accountants
24.1	Power of Attorney (see page 60)
99.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(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.

Table of Contents

- (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 Quarterly Report on Form 10-Q for the quarter ended June 30, 1995.
- (6) Incorporated by reference to exhibits filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended December 27, 1996.
- (7) Incorporated by reference to exhibits filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended December 26, 1997.
- (8) Incorporated by reference to exhibits filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended December 25, 1998.
- (9) Incorporated by reference to exhibits filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended December 24, 1999.
- (10) Incorporated by reference to exhibits filed with Registrant's Annual Report on Form 10-K for the fiscal year ended March 31, 2000.
- (11) Incorporated by reference to exhibits filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended September 28, 2001.
- (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 (333-44980) as declared effective by the Securities and Exchange Commission on August 31, 2000.
- (14) Incorporated by reference to exhibits filed with Registrant's Annual Report on Form 10-K for the fiscal year ended March 30, 2001.
- (15) Incorporated by reference to exhibits filed with Registrant's Registration Statement on Form S-8 (No. 333-98143) as declared effective by the Securities and Exchange Commission on August 15, 2002.
- (16) Incorporated by reference to exhibits filed with Registrant's Report on Form 8-K (File No. 000-20198) filed with the Securities and Exchange Commission on January 6, 2003.
- (17) Incorporated by reference to exhibits filed with Registrant's Annual Report on Form 10-K for the fiscal year ended March 29, 2002.

(b) *Reports on Form 8-K.*

We filed a Report on Form 8-K (File No. 000-20198) with the Securities and Exchange Commission on January 6, 2003 to disclose the terms of our agreement to sell certain assets and assign certain obligations of WellCheck Inc.

(c) *Exhibits.*

See Item 16(a)(3) above.

(d) *Financial Statement Schedules.*

See Item 16(a)(2) above.

Table of Contents**SIGNATURES**

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

CHOLESTECH CORPORATION

By: /s/ WARREN E. PINCKERT II

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

Date: June 25, 2003

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, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ WARREN E. PINCKERT II <hr/> (Warren E. Pinckert II)	President, Chief Executive Officer and Director (Principal Executive Officer)	June 25, 2003
/s/ WILLIAM W. BURKE <hr/> (William W. Burke)	Vice President of Finance, Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)	June 25, 2003
/s/ JOHN H. LANDON <hr/> (John H. Landon)	Director	June 25, 2003
/s/ MICHAEL D. CASEY <hr/> (Michael D. Casey)	Director	June 25, 2003
/s/ JOHN L. CASTELLO <hr/> (John L. Castello)	Director	June 25, 2003
/s/ MOLLY J. COYE <hr/> (Molly J. Coyle)	Director	June 25, 2003

Edgar Filing: CHOLESTECH CORPORATION - Form 10-K

(Molly J. Coye)

/s/ STUART HEAP

Director

June 25, 2003

(Stuart Heap)

/s/ LARRY Y. WILSON

Director

June 25, 2003

(Larry Y. Wilson)

60

Table of Contents

I, Warren E. Pinckert II, certify that:

1. I have reviewed this annual report on Form 10-K of Cholestech Corporation;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officer and I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
 - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
 - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officer and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/ WARREN E. PINCKERT II

Warren E. Pinckert II
President and Chief Executive Officer

Date: June 25, 2003

Table of Contents

I, William W. Burke, certify that:

1. I have reviewed this annual report on Form 10-K of Cholestech Corporation;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officer and I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
 - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
 - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
 - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officer and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/ WILLIAM W. BURKE

William W. Burke
*Vice President of Finance and
Chief Financial Officer*

Date: June 25, 2003

Table of Contents

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 16(a)(1) present fairly, in all material respects, the financial position of Cholestech Corporation and its subsidiary at March 28, 2003 and March 29, 2002, and the results of their operations and their cash flows for each of the three years in the period ended March 28, 2003 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 16(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 18, 2003

F-1

Table of Contents

CHOLESTECH CORPORATION
CONSOLIDATED BALANCE SHEETS

	March 28, 2003	March 29, 2002
<i>(in thousands, except share data)</i>		
Assets		
Current assets:		
Cash and cash equivalents	\$ 8,747	\$ 8,800
Marketable securities	4,776	8,227
Accounts receivable, net	5,195	3,725
Inventories, net	6,806	4,973
Prepaid expenses and other assets	1,989	1,153
Note receivable	250	
Deferred tax assets	2,100	
	<hr/>	<hr/>
Total current assets	29,863	26,878
Property and equipment, net	7,491	7,650
Long-term investments	12,558	5,080
Goodwill, net		3,143
Long-term deferred tax assets	2,100	
	<hr/>	<hr/>
Total assets	\$ 52,012	\$ 42,751
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 3,971	\$ 2,814
Accrued payroll and benefits	3,173	3,100
Other liabilities	140	116
	<hr/>	<hr/>
Total current liabilities	7,284	6,030
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; 13,698,533 and 13,213,503 shares issued and outstanding at March 28, 2003 and March 29, 2002, respectively	82,242	79,200
Accumulated other comprehensive income	73	1
Accumulated deficit	(37,587)	(42,480)
	<hr/>	<hr/>
Total shareholders' equity	44,728	36,721
	<hr/>	<hr/>
Total liabilities and shareholders' equity	\$ 52,012	\$ 42,751
	<hr/>	<hr/>

See accompanying notes to consolidated financial statements.

Table of Contents**CHOLESTECH CORPORATION****CONSOLIDATED STATEMENTS OF OPERATIONS**

Fiscal Year Ended	March 28, 2003	March 29, 2002	March 30, 2001
<i>(in thousands, except per share data)</i>			
Revenue	\$48,541	41,747	32,489
Cost of revenue	20,424	17,040	14,054
Gross profit	28,117	24,707	18,435
Operating expenses:			
Sales and marketing	12,325	10,115	8,287
Research and development	2,958	2,564	2,195
General and administrative	6,491	5,336	4,293
Litigation and other related			1,311
Total operating expenses	21,774	18,015	16,086
Income from operations	6,343	6,692	2,349
Interest and other income, net	438	449	655
Income before taxes	6,781	7,141	3,004
Provision (benefit) for income taxes	(3,934)	289	224
Income from continuing operations	10,715	6,852	2,780
Loss from sale of discontinued operations	(4,445)		
Loss from discontinued operations	(1,377)	(1,302)	(5,386)
Net income (loss)	\$ 4,893	\$ 5,550	\$ (2,606)
Income from continuing operations per share:			
Basic	\$ 0.79	\$ 0.54	\$ 0.23
Diluted	\$ 0.76	\$ 0.50	\$ 0.22
Loss from discontinued operations per share:			
Basic	\$ (0.43)	\$ (0.10)	\$ (0.45)
Diluted	\$ (0.41)	\$ (0.10)	\$ (0.43)
Net income (loss) per share:			
Basic	\$ 0.36	\$ 0.44	\$ (0.22)
Diluted	\$ 0.35	\$ 0.40	\$ (0.21)
Shares used to compute net income (loss) per share:			
Basic	13,551	12,658	12,046
Diluted	14,077	13,730	12,416

See accompanying notes to consolidated financial statements.

Table of Contents**CHOLESTECH CORPORATION****CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS EQUITY**

	Common Stock		Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total
	Shares	Amount			
<i>(in thousands, except share data)</i>					
Balance at March 31, 2000	11,921,251	\$71,959	\$ (59)	\$(45,424)	\$26,476
Net loss				(2,606)	(2,606)
Change in unrealized gain on available- for-sale securities			128		128
Comprehensive loss					(2,478)
Issuance of Common Stock pursuant to employee stock purchase plan and exercise of stock options	128,386	560			560
Issuance of Common Stock pursuant to Health Net purchase	51,010	300			300
Balance at March 30, 2001	12,100,647	72,819	69	(48,030)	24,858
Net income				5,550	5,550
Change in unrealized gain on available- for-sale securities			(68)		(68)
Comprehensive income					5,482
Issuance of Common Stock pursuant to employee stock purchase plan and exercise of stock options	1,090,701	6,220			6,220
Issuance of Common Stock pursuant to net exercise of warrants	22,155				
Stock compensation acceleration charge		161			161
Balance at March 29, 2002	13,213,503	79,200	1	(42,480)	36,721
Net income				4,893	4,893
Change in unrealized gain on available- for-sale securities			96		96
Change in future currency contracts			(24)		(24)
Comprehensive income					4,965
Issuance of Common Stock pursuant to employee stock purchase plan and exercise of stock options	498,475	3,218			3,218
Purchase of treasury stock	(13,425)	(176)			(176)
Balance at March 28, 2003	13,698,553	\$82,242	\$ 73	\$(37,587)	\$44,728

See accompanying notes to consolidated financial statements.

Table of Contents**CHOLESTECH CORPORATION****CONSOLIDATED STATEMENTS OF CASH FLOWS**

Fiscal Year Ended	March 28, 2003	March 29, 2002	March 30, 2001
<i>(in thousands)</i>			
Cash Flows From Operating Activities:			
Net income (loss)	\$ 4,893	\$ 5,550	\$ (2,606)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation and amortization	2,553	2,608	3,471
Change in allowance for doubtful accounts	59	163	224
Change in inventory reserve	92	30	107
Change in allowance for sales returns	(20)	(58)	
Impairment charge			1,958
Change in accrued net deferred tax asset	(4,200)		
Loss on sale of WellCheck	4,445		
Stock acceleration charge	(72)	161	
Changes in assets and liabilities:			
Accounts receivable	(1,509)	(816)	(1,394)
Inventories	(1,941)	(1,345)	(51)
Prepaid expenses and other assets	(845)	(435)	188
Other assets			(21)
Accounts payable and accrued liabilities	461	(224)	85
Accrued payroll and benefits	(227)	1,200	337
Payment of legal settlement		(855)	
Other liability	24	25	
	<u>3,713</u>	<u>6,004</u>	<u>2,298</u>
Cash Flows From Investing Activities:			
Restricted cash			1,000
Purchases of marketable securities	(49,427)	(36,867)	(11,166)
Maturities of marketable securities	45,472	31,805	9,763
Acquisition of Health Net assets			(1,179)
Purchase of property and equipment	(2,925)	(2,414)	(4,183)
	<u>(6,880)</u>	<u>(7,476)</u>	<u>(5,765)</u>
Cash Flows From Financing Activities:			
Issuance of common stock	3,218	6,220	560
Purchase of treasury stock	(104)		
	<u>3,114</u>	<u>6,220</u>	<u>560</u>
Net increase (decrease) in cash and cash equivalents	(53)	4,748	(2,907)
Cash and cash equivalents at beginning of year	8,800	4,052	6,959
	<u>\$ 8,747</u>	<u>\$ 8,800</u>	<u>\$ 4,052</u>
Supplemental disclosures of cash flow information and non-cash transactions:			
Cash paid for income taxes	\$ 59	\$ 160	\$ 300
Common stock issued for Health Net acquisition			300

See accompanying notes to consolidated financial statements.

Table of Contents

**CHOLESTECH CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

1. Summary of Significant Accounting Policies

Description of the Company

Cholestech Corporation (the Company) was incorporated in California on February 2, 1988. Until December 23, 2002, when the Company sold its WellCheck business, the Company engaged in two business activities:

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

WellCheck™ conducted consumer testing within the United States to help assess the risk for heart disease and other chronic diseases. Through its Test Event Activity Management Software (TEAMS), WellCheck collected test results and other patient data and aggregated that data for testing event sponsors use in marketing programs. As discussed in note 2, in December 2002, the Company sold WellCheck to ImpactHealth. As a result of the sale, the operations of WellCheck have been accounted for as discontinued operations in accordance with Financial Accounting Standards Board Statement (SFAS) No. 144 *Accounting for the Impairment or Disposal of Long-Lived Assets* and Accounting Principles Board (APB) Opinion No. 30. *Reporting the Results of Operations - Reporting the Effects of Disposal of a Segment of a Business, an Extraordinary, Unusual and Infrequent Occurring Events and Transactions*. Amounts in the consolidated financial statements of operations and related notes for all periods shown have been reclassified to reflect the presentation of discontinued operations.

Fiscal year end

The Company's fiscal year is a 52 week period ending on the last Friday in March. Fiscal 2003, 2002 and 2001 were comprised of 52 weeks.

Principles of consolidation

The consolidated financial statements include the accounts of the Company and the accounts of WellCheck its wholly owned subsidiary, through December 23, 2002. All significant intercompany transactions and balances have been eliminated in consolidation.

Revenue recognition

The Company recognizes revenue from product sales when there is pervasive evidence that an arrangement exists, title has transferred to our customers, the price is fixed and determinable and collection is reasonably assured. Provisions for discounts to customers, returns or other adjustments are provided for in the same period that the related product sales are recorded based upon analyses of

Table of Contents

historical discounts and returns. The Company recognizes revenue associated with testing services upon completion of the services to be performed under contract when all obligations are satisfied, and collection is reasonably assured.

The Company offers an early payment discount to certain customers.

The Company maintains a warranty allowance for the estimated amount of repairs or replacement cost of all products which are found to be defective. Provisions for warranty are provided for in the same period that the related product sales are recorded. The amount of allowance is based upon analyses of historical repairs and replacements.

The Company maintains a product return allowance for the estimated amount of returns allowed by contract to some customers. Provisions for returns are provided for in the same period that the related product sales are recorded. The amount of allowance is based upon analyses of returns and customer contracts.

Shipping and handling charges are invoiced to customers based on the amount of products sold. Shipping and handling fees are recorded at the time of revenue recognition, and are included in revenue.

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 28, 2003 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 their fair market value at the balance sheet date. Realized gains and losses on sales of all such securities are reported in earnings and are computed using the specific identification cost method. Unrealized gains and losses on 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 \$96,000 in unrealized gains as of March 28, 2003 included in accumulated other comprehensive income in shareholders' equity and \$1,000 in unrealized gains as of March 29, 2002.

Table of Contents

The cost and fair market value of available-for-sale securities at March 28, 2003 are as follows (in thousands):

	Cost	Unrealized Gain (Loss)	Fair Market Value	Maturity date
Short-term marketable securities				
Commercial paper	\$ 1,529	\$ 4	\$ 1,533	November 2003 February 2004
Corporate bonds	714	4	718	May 2003 March 2004
Government agency	2,525		2,525	August 2003 February 2004
	<u>4,768</u>	<u>8</u>	<u>4,776</u>	April 2003 December 2003
Long-term marketable securities				
Corporate bonds	\$ 8,391	\$ 84	\$ 8,475	April 2004 October 2007
Government agency	4,079	4	4,083	May 2005 October 2005
	<u>12,470</u>	<u>88</u>	<u>12,558</u>	

The cost and fair market value of available-for-sale securities at March 29, 2002 are as follows (in thousands):

	Cost	Unrealized Gain (Loss)	Fair Value	Maturity date
Short-term marketable securities				
Commercial paper	\$3,106		\$3,106	April May 2002
Corporate bonds	1,571	(3)	1,568	May 2002 February 2003
Government agency	3,502	51	3,553	November 2002 February 2003
	<u>8,179</u>	<u>48</u>	<u>8,227</u>	
Long-term marketable securities				
Corporate bonds	\$2,059	\$(19)	\$2,040	April July 2003
Government agency	3,068	(28)	3,040	September 2003 February 2004
	<u>5,127</u>	<u>\$(47)</u>	<u>5,080</u>	

Derivative Instruments

In the first quarter of fiscal 2002, the Company adopted SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities* which establishes accounting and reporting standards for derivative instruments and for hedging activities. SFAS 133 requires that an entity recognize all derivatives as

Table of Contents

either assets or liabilities on the balance sheet and measure those instruments at fair value. The accounting for changes in the fair value of a derivative depends upon the intended use of the derivative and the resulting designation. For a derivative designated as a fair value hedge, the gain or loss is recognized in earnings in the period of change together with the offsetting loss or gain on the hedged item attributed to the risk being hedged. For a derivative designated as a cash flow hedge, the effective portion of the derivative's gain or loss is initially reported as a component of accumulated other comprehensive income (loss) in shareholder's equity and subsequently reclassified into earnings when the related inventory is sold and the hedged exposure affects earnings. If the transaction being hedged fails to occur, a forecasted transaction being hedged is no longer expected to occur, or the hedging is determined to be ineffective, the gain or loss on the associated financial instrument is recorded immediately in earnings.

The Company uses financial instruments, such as forward exchange contracts, to hedge a portion of certain existing and anticipated foreign currency denominated transactions expected to occur within 12 months. The terms of currency instruments used for hedging purposes are generally consistent with the timing of the transactions being hedged. The Company enters into foreign currency forward exchange contracts to manage foreign currency exposures arising from inventory purchases and accounts payable denominated in foreign currencies. The Company does not use derivative financial instruments for trading or speculative purposes.

At March 28, 2003, the Company had outstanding forward contracts to purchase £1.6 million for approximately \$2.6 million. The open contracts mature at various dates through December 18, 2003 and hedge certain forecasted inventory purchases denominated in the British Pound Sterling. The unrealized loss on the forward contracts at March 28, 2003 was \$24,000, all of which is expected to be reclassified to earnings within the next 12 months. There was no gain or loss recorded in the period from hedge ineffectiveness or from forecasted transactions no longer expected to occur.

Certain risks and uncertainties

Financial instruments that potentially subject the Company to credit risk consist of cash and cash equivalents, marketable securities accounts receivable and forward currency contracts. Cash and 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 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.

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. Provisions are made for estimated product returns, which historically have been immaterial. In fiscal 2003, two customers accounted for \$10.9 million or 22% of total revenue and \$4.5 million or 9% of total revenue, compared to fiscal 2002, when one customer accounted for

Table of Contents

\$8.6 million or 20% of total revenue. At March 28, 2003, two customers accounted for \$848,000, or 16%, of total accounts receivable and \$626,000, or 12% of total accounts receivable, respectively. At March 29, 2002, two customers accounted for \$622,000, or 17%, 398,000 or 11%, of total accounts receivable, respectively.

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

In June 2001, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 141, *Business Combinations* (SFAS 141) which establishes how business combinations initiated after June 30, 2001 must be accounted for using the purchase method. The Company adopted SFAS No. 141 beginning with the quarter ended June 29, 2001; such adoption had no impact on the financial reporting and related disclosures of the Company.

In July 2001, the FASB issued SFAS No. 142, *Goodwill and Other Intangible Assets* (SFAS 142), which establishes financial accounting and reporting for acquired goodwill and other intangible assets and supersedes Accounting Principles Board (APB) Opinion No. 17, *Intangible Assets*. It addresses how intangible assets that are acquired individually or with a group of other assets should be accounted for in financial statements upon their acquisition and thereafter. The Company elected to adopt SFAS No. 142 beginning with the first quarter of fiscal 2002. The Company has reviewed its goodwill for impairment and determined that no impairment loss existed on March 30, 2001, June 29, 2001 and March 29, 2002. All goodwill related to the Company's WellCheck division which was sold in December 2002.

Table of Contents*Research and development*

Research and development costs are expensed as incurred.

Warranties

The Company records an accrual for estimated warranty costs when revenue is recognized. Warranty covers cost of repair of the LDX Analyzer, and to replace defective single-use test cassettes. The warranty period of the LDX Analyzer is one year and single use test cassettes are warranted for the self-life of the product. The warranty cost of the GDY Analyzer and test cartridges are the responsibility of the vendor. The Company has processes in place to estimate accruals for warranty exposure. The processes include estimated LDX Analyzer failure rates, costs to repair the analyzer and estimated replacement rates for single use test cassettes. Although the Company believes it has the ability to reasonably estimate warranty expenses, unforeseeable changes in factors impacting the estimate for warranty could occur and such changes could cause a material change in the Company's warranty accrual estimate. Such a change would be recorded in the period in which the change was identified. Changes in the Company's product warranty liability during the year ended March 28, 2003 were as follows (in thousands):

	Year Ended March 2003
Balance at the beginning of the year	\$ 116
Accruals and charges for warranty for the year	391
Cost of repairs and replacements	(391)
	<hr/>
Balance at the end of the year	\$ 116
	<hr/>

Advertising costs

The cost of advertising is expensed as incurred. Advertising expenses were \$175,000, \$263,000 and \$453,000 for fiscal 2003, 2002 and 2001, respectively.

Income taxes

The Company uses the asset and liability method of accounting for income 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 in fiscal 2003 included a \$4.2 million gain from an income tax benefit which resulted from the reversal of a portion of the valuation allowance previously established for the Company's net operating losses. The Company continually reviews the adequacy of its valuation allowance, primarily based on its estimates of future taxable income. Changes in the Company's assessment of the adequacy of the valuation allowance could give rise to an increase or reduction in the valuation allowance and a tax benefit or expense in the period of the change.

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 of Contents

table reconciles the numerator (net income or loss) and denominator (number of shares) used in the basic and diluted per share computations.

	March 28, 2003	March 29, 2002	March 30, 2001
<i>(in thousands, except share data)</i>			
Income			
Income from continuing operations	\$ 10,715	\$ 6,852	\$ 2,780
Loss from discontinued operations	(5,822)	(1,302)	(5,386)
Net Income (loss)	<u>\$ 4,893</u>	<u>\$ 5,550</u>	<u>\$ (2,606)</u>
Shares			
Basic	13,551	12,658	12,046
Effect of dilutive securities	526	1,072	370
Diluted	<u>14,077</u>	<u>13,730</u>	<u>12,416</u>
Per share continuing operations			
Basic	\$ 0.79	0.54	\$ 0.23
Effect of dilutive securities	(0.03)	(0.04)	(0.01)
Diluted	<u>\$ 0.76</u>	<u>\$ 0.50</u>	<u>\$ 0.22</u>
Per share discontinued operations:			
Basic	\$ (0.43)	\$ (0.10)	\$ (0.45)
Effect of dilutive securities	(0.02)	(0.02)	(0.02)
Diluted	<u>\$ (0.41)</u>	<u>\$ (0.10)</u>	<u>\$ (0.43)</u>
Per share continuing operations:			
Basic	\$ 0.36	\$ 0.44	\$ (0.22)
Effect of dilutive securities	(0.01)	(0.04)	0.01
Diluted	<u>\$ 0.35</u>	<u>\$ 0.40</u>	<u>\$ (0.21)</u>

At March 28, 2003, options to purchase 1,811,253 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. At March 29, 2002, options to purchases 472,950 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. Options to purchase 2,711,304 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 at March 30, 2001.

Fair value of financial instruments

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

Table of Contents*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 estimates.

Accounting for stock-based compensation

The Company accounts for its stock-based compensation plans in accordance with SFAS No. 123, *Accounting for Stock-Based Compensation* as amended by SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*. As permitted under SFAS No. 148, the Company uses the intrinsic value-based method of Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, to account for its employee stock-based compensation plans. Under APB Opinion No. 25, compensation expense is based on the difference, if any, on the date of grant, between the fair value of the Company's common shares and the exercise price of the option. Compensation costs for stock options, if any, is realized ratably over the vesting period.

The Company provides additional proforma disclosures required by SFAS No. 123 as amended by SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure An Amendment of SFAS No. 123*. 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:

	March 28, 2003	Fiscal Year Ended March 29, 2002	March 30, 2001
<i>(in thousands, except per share data)</i>			
Net income (loss) as reported	\$ 4,893	\$ 5,550	\$(2,606)
Deduct: total stock-based employee compensation expense determined under fair value based method for all awards	(2,273)	(1,110)	(1,490)
Net income (loss) pro forma	\$ 2,620	\$ 4,440	\$(4,096)
Net income (loss) per share:			
As reported basic	\$ 0.36	\$ 0.44	\$ (0.22)
Pro forma basic	\$ 0.19	\$ 0.35	\$ (0.34)
As reported diluted	\$ 0.35	\$ 0.40	\$ (0.21)
Pro forma diluted	\$ 0.19	\$ 0.32	\$ (0.33)

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 1.5%, 2.5% and 5.9% for options granted during fiscal 2003, 2002 and 2001, respectively; volatility factors of 95%, 81% and 88% for options granted during fiscal 2003, 2002 and 2001, respectively; and a weighted average expected option term of

Table of Contents

7.0 years for fiscal 2003, 2002 and 2001. The weighted average per share fair value of stock options granted in fiscal 2003, 2002 and 2001 was \$8.33, \$9.34 and \$5.37 per share, respectively.

The fair value of stock purchase rights is estimated using the Black-Scholes valuation model with the following assumptions for fiscal 2003, 2002 and 2001, respectively; dividend yield of 0.0% for all periods; an expected life of six months for all periods; expected volatility factors of 69%, 81% and 93% for fiscal 2003, 2002 and 2001, respectively. The weighted average per share value of stock purchase rights granted in fiscal 2003, 2002 and 2001 was \$1.72, \$1.21 and \$1.28 per share, respectively. The weighted average per share exercise price of stock purchase rights granted in fiscal 2003, 2002 and 2001 was \$6.46, \$6.13 and, \$5.05, respectively.

The pro forma effect on net income (loss) and net income (loss) per share for fiscal 2003, 2002 and 2001 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.

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 above.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS 123 and EITF 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 FASB Interpretation No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plan* (FIN 28).

Reclassifications

Certain financial statements 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 July 2002, the FASB issued SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, which supersedes the Emerging Issues Task Force (EITF) Issue No. 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)*. This new standard requires companies to recognize costs associated with exit or disposal activities when the costs are incurred rather than at the date of a commitment to an exit disposal plan. Costs covered by the standard include lease termination costs and certain employee severance costs that are associated with a restructuring, discontinued operation, plant closing, or other exit or disposal activity. This standard is effective for exit or disposal activities that are initiated after December 31, 2002. The Company adopted this standard and the adoption of this standard had no material impact on its financial statements.

In November 2002, the FASB issued FASB Interpretation No. 45 (FIN 45), *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*. FIN 45 requires that a liability be recorded in the guarantor's balance sheet upon issuance of a guarantee. In addition, FIN 45 requires disclosures about the guarantees that an entity has issued,

Table of Contents

including a reconciliation of changes in the entity's product warranty liabilities. The initial recognition and initial measurement provisions of FIN 45 are applicable on a prospective basis to guarantees issued or modified after December 31, 2002, irrespective of the guarantor's fiscal year-end. The disclosure requirements of FIN 45 are effective for financial statements of interim or annual periods ending after December 15, 2002. The Company adopted this standard and the adoption of this standard had no material impact on its financial statements.

In November 2002, EITF reached a consensus on Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*. EITF Issue No. 00-21 provides guidance on how to account for arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The provisions of EITF Issue No. 00-21 will apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The Company believes that the adoption of this standard will have no material impact on its financial statements.

In January 2003, the FASB issued FASB Interpretation No. 46 (FIN 46), *Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51*. FIN 46 requires certain variable interest entities to be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 is effective immediately for all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the provisions of FIN 46 must be applied for the first interim or annual period beginning after June 15, 2003. The Company believes that the adoption of this standard will have no material impact on its financial statements.

2. Sale of WellCheck

On December 23, 2002, the Company completed the sale of certain assets and the assignment of certain obligations of its wholly owned subsidiary WellCheck, Inc. (WellCheck). The sale was made pursuant to the terms and conditions of a Stock Purchase Agreement (the Agreement) dated December 23, 2002 by and among the Company, WellCheck and ImpactHealth.com, Inc. Under the terms of the Agreement, the Company received a secured promissory note in the aggregate principal amount of \$250,000 (the Note) due on December 23, 2003, the right to receive an additional \$200,000 contingent upon the attainment of certain performance measures and a royalty per participant tested with the TEAMS for three years after the date of the agreement. As a result of the sale, the operations of WellCheck have been accounted for as discontinued operations in accordance with SFAS No. 144 *Accounting for the Impairment or Disposal of Long-Lived Assets* and APB No 30. *Reporting the Results of Operations - Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions*. Amounts in the consolidated financial statements and related notes for all periods shown have been reclassified to reflect the presentation of discontinued operations.

Operating results for the discontinued operations are reported, net of tax, under loss from discontinued operations in the accompanying consolidated statements of operations.

Table of Contents

	March 28, 2003	March 29, 2002	March 30, 2001
Revenue	\$ 186	\$ 5,619	\$ 4,514
Loss before provision for income taxes	(1,489)	(1,356)	(5,611)
Income tax benefit	112	54	225
Net loss	<u>\$ (1,377)</u>	<u>\$ (1,302)</u>	<u>\$ (5,386)</u>

Contingent sale proceeds, including TEAMS royalty and performance remuneration, will be recognized as earned as a component of discontinued operations.

As a result of the sale, the Company recorded a loss of \$4.4 million. The components of the loss are as follows (in thousands):

Net book value of WellCheck assets and costs related to the sale	\$4,695
Less note receivable	<u>(250)</u>
Net loss	<u>\$4,445</u>

3. Balance Sheet Composition

Accounts receivable consist of (in thousands), net:

	March 28, 2003	March 29, 2002
Accounts receivable	\$5,376	\$3,869
Less allowance for sales returns	(5)	(25)
Less allowance for doubtful accounts	<u>(176)</u>	<u>(119)</u>
	<u>\$5,195</u>	<u>\$3,725</u>

Inventories consist of (in thousands), net:

	March 28, 2003	March 29, 2002
Raw materials	\$2,388	\$1,573
Work-in-progress	1,762	1,613
Finished goods	<u>2,656</u>	<u>1,787</u>
	<u>\$6,806</u>	<u>\$4,973</u>

Table of Contents

Property and equipment consist of (in thousands), net:

	March 28, 2003	March 29, 2002
Machinery, equipment and TEAMS software	\$ 14,149	\$ 13,454
Furniture and fixtures	416	411
Computer equipment	2,075	2,595
Leasehold improvements	2,261	1,315
Patents	111	111
Construction-in-progress	153	565
	<u>19,165</u>	<u>18,451</u>
Less accumulated depreciation and amortization	(11,674)	(10,801)
	<u>\$ 7,491</u>	<u>\$ 7,650</u>

Depreciation and amortization expense of \$2.6 million was incurred in fiscal 2003, \$2.6 million in fiscal 2002 and \$2.8 million in fiscal 2001.

Goodwill consists of (in thousands):

	March 28, 2003	March 29, 2002
Cost	\$	\$3,952
Less accumulated amortization	<u>—</u>	<u>(809)</u>
	<u>\$</u>	<u>\$3,143</u>

All goodwill was related to the Company's WellCheck subsidiary which was sold in December 2002. During fiscal 2001, total goodwill amortization was \$709,000.

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

	March 28, 2003	March 29, 2002
Trade accounts payable	\$2,518	\$1,564
Accrued accounting and reporting	379	330
Accrued royalties	274	263
Accrued legal expenses	261	97
Accrued rent	165	29
Accrued income tax	139	79
Accrued distributor incentives	69	218
Other accrued liabilities	166	234
	<u>\$3,971</u>	<u>\$2,814</u>

Table of Contents

4. Borrowing Arrangements

In July 2001, the Company entered into an agreement with its primary bank for an \$8 million revolving line of credit. While the 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 either the Company's choice of 0.5% below the bank's prime rate or 1.75% above the LIBOR rate, depending on the payment schedule. The line of credit agreement expires on July 1, 2003. As of March 28, 2003 and March 29, 2002, there were no borrowings outstanding under the line of credit.

5. Commitments and Contingencies

Leases

The Company leases office and laboratory facilities under non-cancelable operating leases. The lease for the Company's headquarters facility was renewed during fiscal 2002 and currently expires in March 2007 with an option to extend the lease for an additional three years. On July 1, 2002, the Company leased approximately 29,000 additional square feet of its headquarters facility, bringing the total leased space to approximately 69,000 square feet. The Company leased a second facility approximately 7,200 square foot in Hayward during fiscal 2001, which will expire in October 2003. In February 2002, in conjunction with the sale of WellCheck, the Company negotiated a buyout of its Oakland facility, terminating a lease which would have expired in October 2005. Rent expense was \$1.3 million, \$765,000 and \$609,000 for fiscal 2003, 2002 and 2001, respectively. The Company believes that its existing facilities are adequate for the present and that additional space will be available as needed.

Total future minimum payments required under the Company's non-cancelable operating leases at March 29, 2003 were \$1.0 million, \$1.0 million, \$1.1 million and \$1.1 million for fiscal 2004, 2005, 2006 and 2007, respectively.

License and development agreements

The Company has obtained rights to use certain technology in 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 2003, 2002 and 2001 was \$753,000, \$755,000 and \$490,000, respectively, and was charged to cost of product revenue.

Litigation

On August 2, 2002, N.V. Euromedix (Euromedix) filed suit against the Company in the Commercial Court in Leuven Belgium (No. F5700-02), seeking damages for the wrongful termination of an implied distribution agreement with the Company for Europe and parts of the Middle East. On November 7, 2002, the court dismissed the suit. On December 31, 2002, Euromedix filed suit against us in the Commercial Court in Leuven Belgium (No. F8756-02), seeking damages in the amount of approximately 3.5 million for the wrongful termination of an implied distribution agreement with our company for Europe and parts of the Middle East. A hearing was held on April 29, 2003 regarding certain procedural issues. In a judgment rendered on May 27, 2003, the Court referred the complaint to the Constitutional Court before rendering a final decision. The Court asked the Constitutional Court to

Table of Contents

render an opinion regarding certain constitutional issues related to the trademark infringement arguments the Company raised at the hearing. A hearing is scheduled to be held in the Commercial Court on July 8, 2003. The Company believes these claims are without merit and intend to continue to defend the claims vigorously.

On February 5, 1999, a complaint entitled *Ree v Pinckert et al.* No. C99-0562 (PJH) was filed in the United States District Court for the Northern District of California. The action was a class action and the complaint alleged that the Company and certain of its current and former officers violated the federal securities laws by making false and misleading statements concerning the Company and its business during the period of June 12, 1996 through June 25, 1998. On June 14, 2001, the Company executed an agreement in principle with plaintiffs to resolve this matter for a payment of \$3.0 million by its insurance carrier. The Company recorded a \$1.3 million charge during the fiscal year ended March 30, 2001 for legal fees and insurance costs related to resolution of this matter. The Company paid \$855,000 to its insurance carrier and \$121,000 for legal fees in the quarter ended June 29, 2001. The settlement received court approval on October 31, 2001.

On December 23, 1999, Roche Diagnostics GmbH (Roche) filed suit against the Company and two of its distributors, Health Care Solutions AG and Euromedix N.V./ SA, in the Canton Court of the Canton Zug in Zug, Switzerland (No. ES580/1999), seeking a cease and desist order barring the Company from selling HDL assay single-use test cassettes in Switzerland. The complaint alleges that the Company violated a Roche European patent for HDL. On July 11, 2000, the court denied Roche's request for an injunction and ordered it to pay a portion of the Company's legal fees. On May 2, 2002, in response to the Company's motion, the court ruled that it did not have local jurisdiction over the matter and ordered Roche to pay the Company's legal fees. Roche subsequently appealed the May 2, 2002 decision by the Canton Court of the Canton Zug. On October 7, 2002, the Swiss Federal Tribunal referred the matter back to the Canton Court but rejected the jurisdiction aspect of Roche's appeal. At this point in time, no schedule has been set regarding additional court activity. The Company believes the claim is without merit and intends to continue to defend the claim vigorously.

In January 2000, Roche filed suit against the Company and two of its distributors, Micro-Medical GmbH and Euromedix N.V./SA, in the District Court in Dusseldorf, Germany (No. 4aO4/00), seeking a cease and desist order barring the Company from selling HDL single-use test cassettes in Germany. The complaint alleges the Company violated a Roche German priority patent for HDL by selling its single-use test cassette containing a HDL assay in Germany. On December 4, 2001, a hearing was held in Dusseldorf, Germany at which witnesses for Roche and the Company testified. On October 29, 2002, the District Court held a hearing on the merits of the case. The court rendered its decision on December 19, 2002, ruling that (i) the Company is not allowed to further distribute HDL test cassettes which correspond to the German Roche patent, (ii) the Company's distributors must destroy HDL products in their possession, (iii) the Company and its distributors are subject to unspecified damages based on all sales which occurred in Germany since December 8, 1995 and (iv) the Company and its distributors must pay the legal fees of the litigation. However, the decision is not enforceable until Roche posts a bond of security in the amount of 2.5 million, approximately \$2.7 million. Roche has not yet posted the bond, nor has it notified the Company of an intention to post the bond. On January 10, 2003, the Company appealed this ruling with the Appeal Court in Dusseldorf. The Company believes the claim is without merit and intends to continue to defend the claim vigorously.

On August 2, 2000, the Company filed suit against Roche in the Federal Patent Court in Munich, Germany (No. 3 Ni 40/00), seeking the nullification of Roche's German patent for measurement of HDL.

Table of Contents

cholesterol. On December 6, 2001, a hearing was held on the merits of the nullification complaint. The court partially voided the Roche German patent while clarifying the remaining claim with additional restrictions. On February 20, 2002, the Company filed an appeal with the Federal Supreme Court.

In September 2000, Roche filed suit against the Company and one of its distributors in the Commercial Court in Vienna, Austria (No. Ei/Ti ROCH 04002), seeking a cease and desist order barring the Company from distributing HDL assay single-use test cassettes in Austria. The complaint alleges that the Company violated a Roche European patent for HDL. On August 9, 2002, the court ruled in the Company's favor and dismissed the patent infringement claim. There can be no assurance as to whether Roche will take any additional action.

On March 3, 2003, Roche Diagnostics Corporation and Roche Diagnostics GmbH filed suit against the Company in the United States District Court for the Southern District of Indiana (Indianapolis) (No. CV-0303LJM-WTL), seeking a preliminary and permanent injunction, damages and attorneys fees for patent infringement. The plaintiffs have not yet served the Company with this complaint and the Company is currently in discussions with the plaintiffs. The complaint alleges that the Company is violating three Roche U.S. patents for HDL. The Company believes the claim is without merit and intends to defend the claim vigorously.

Based upon consultation with outside counsel handling the Company's defense in these matters and a discussion of potential results, the Company does not consider a negative outcome to be probable and has not accrued any amounts for potential losses related to these proceedings. Because of uncertainties related to both the amount and range of loss on the pending litigation, management is unable to make a reasonable estimate of the liability that could result from an unfavorable outcome. As additional information becomes available, the Company will assess the potential liability related to its pending litigation. The Company will record accruals for losses if and when the Company determines the negative outcome of such matters to be probable and reasonably estimable. The Company's estimates regarding such losses could differ from actual results. Revisions in the Company's estimates of the potential liability could materially impact the Company's results of operations and financial position.

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

6. Restructuring Accruals

During third quarter of fiscal year 2003, the Company recorded a restructuring charge of approximately \$591,000 which included wages, severance and other related costs for two executives and two staff members whose employment was terminated as a result of the divestiture of the Company's WellCheck testing services business. The accrual represents costs recognized pursuant to EITF 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (Including Certain Costs Incurred in a Restructuring)* and SAB 100, *Restructuring and Impairment Charges*. The restructuring accrual is included on the balance sheet within the accrued payroll and benefits. During fiscal 2003, the Company made payments of \$50,000 to employees terminated under the restructuring plan, and incurred \$17,000 of other related costs. As of March 29, 2003 approximately \$524,000 in remaining costs are expected to be paid in fiscal 2004 under the restructuring plan.

F-20

Table of Contents

7. 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 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 28, 2003, nor was there any activity relating to preferred stock during the three year period ended March 28, 2003.

Stock incentive program

In August 1997, the shareholders approved the 1997 Stock Incentive Program (the 1997 Program) which provides incentive stock options (ISOs) and non-qualified stock options (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. 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% each year. Vesting of individual option grants may be accelerated on the occurrence of certain events as described in the stock option agreement. As of March 28, 2003, 3,192 shares were 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 ten 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, 2,000,000 shares of common stock are reserved for issuance. As of March 28, 2003, 481,784 shares were available for future grant.

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 ten 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 of certain events as described in the stock option agreement. Pursuant to the terms of the 2000 Program, 1,195,000 shares of common stock are reserved for future issuance. As of March 28, 2003, 255,170 shares were available for future grant.

Table of Contents

Stock option activity under the programs is as follows:

	Outstanding Options	Weighted Average Exercise Price Per Share
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
	<hr/>	
Balance, March 30, 2001	2,711,304	6.28
Granted	970,789	12.53
Exercised	(1,057,273)	5.69
Canceled	(136,655)	7.85
	<hr/>	
Balance, March 29, 2002	2,488,165	8.88
Granted	615,200	10.38
Exercised	(438,823)	6.45
Canceled	(259,820)	12.02
	<hr/>	
Balance, March 28, 2003	2,404,722	9.37
	<hr/>	

The following table summarizes information about stock options outstanding at March 28, 2003:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number	Weighted Avg. Contractual Life	Weighted Avg. Exercise Price	Number	Weighted Avg. Exercise Price
\$ 2.00 \$ 6.26	593,469	4.4	\$ 4.94	428,359	\$ 5.01
\$ 6.27 \$ 7.75	654,004	7.3	7.58	363,159	6.72
\$ 7.76 \$11.87	561,353	7.3	8.83	167,933	10.07
\$11.88 \$17.85	595,896	8.8	16.24	158,833	16.06
	<hr/>			<hr/>	
	2,404,722	7.0	9.37	1,118,284	8.19
	<hr/>			<hr/>	

Employee stock purchase plan

In April 1992, the shareholders approved 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

Table of Contents

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 18,732, 33,428 and 37,232 shares of common stock to employees in fiscal 2003, 2002 and 2001, respectively. The Stock Purchase Plan terminated in June 2002.

In August 2002, the shareholders approved the 2002 Employee Stock Purchase Plan (the ESPP), effective September 1, 2002, which reserved 400,000 shares of its common stock to be issued in accordance with the Internal Revenue Code under such terms as approved by the board of directors. The ESPP has a series of consecutive, overlapping 24-month offering periods, which each offering period consisting of four six-month purchase periods. Under the terms of the ESPP, 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 first trading day of the offering period or the last trading day of the purchase period. Under the ESPP, the Company sold 40,920 shares of common stock to employees in fiscal 2003.

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) ten days (or such later date as may be determined by a majority of the board of directors) following a public announcement that a person or group of affiliated or associated persons has acquired, or obtained the right to acquire, beneficial ownership of 15% or more of the Company's outstanding common stock or (ii) ten business days following the commencement of, or announcement of an intention to make, a tender offer or exchange offer, the consummation of which would result in the beneficial ownership by a person or group of 15% or more of the Company's outstanding common stock. The Rights expire on the earlier of (i) January 22, 2007 or (ii) redemption or exchange of the Rights.

Warrants

In October 2001, we issued 22,155 shares of common stock pursuant to a net exercise of warrants. As of March 28, 2003, we had no outstanding warrants.

Stock options acceleration charge

During fiscal 2002, two executives terminated their employment with the Company. The vesting of a portion of their stock options was accelerated, allowing the executives to purchase option shares that would otherwise have expired unvested, resulting in a \$161,000 charge to operating expense. During fiscal 2003, the Company reached an agreement with one of these executives to reacquire a portion of these option shares, at an amount less than the fair market value of the stock resulting in a recovery of \$72,000 of the charge recognized in 2002.

Table of Contents**8. 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 \$11,000 per year during calendar year 2002, up from \$10,500 in prior years, and employees over 50 years of age may elect to contribute an additional \$1,000 (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 \$0, \$620,000 and \$261,000 in fiscal 2003, 2002 and 2001, respectively.

9. Income Taxes

A benefit for income taxes of \$4,046,000, which includes a current payable of \$154,000, was recorded for the fiscal year ended March 28, 2003. \$4.2 million of the tax benefit relates to a release of valuation allowance due to the expected future utilization of net operating loss. A provision for income taxes of \$235,000, all of which is current, was recorded for the fiscal year ended March 29, 2002. No provision was recorded for the fiscal year ended March 30, 2001 as the Company incurred a net operating loss for income tax purposes.

The differences between the federal statutory income tax rate and the Company's effective tax rate for fiscal 2003 and 2002 are as follows:

Fiscal Year Ended	March 28, 2003	March 29, 2002
Provision at statutory rate	34.0%	34.0%
State taxes, net of federal benefit	5.8	5.8
Stock options	(8.5)	(10.2)
Meals and entertainment expense	11.9	
Utilization of research and development credits	(62.4)	
Valuation allowance, current	8.0	(26.4)
Change in valuation allowance	(495.8)	
Alternative minimum Tax	12.9	
Prior year tax adjustments	11.3	
Other	5.5	0.8
	(477.3)%	4.0%

The difference between the federal statutory income tax rate and the Company's effective tax rate for fiscal 2002 relates primarily to losses for which no benefit was recognized. The difference between the federal statutory income tax rate and the Company's effective tax rate for fiscal 2003 relates primarily to changes in valuation allowance for which a benefit was recognized.

Table of Contents

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

	March 28, 2003	March 29, 2002	March 30, 2001
Net operating loss carryforwards	\$ 11,491	\$ 12,708	\$ 15,334
Research and development tax credit carryforwards	2,240	2,214	2,641
Minimum tax credit carryforwards	56	95	164
Capitalized research and development	948	786	920
Other	56	1,610	(100)
Valuation allowance for deferred tax assets	(10,591)	(17,413)	(18,959)
	<u>\$ 4,200</u>	<u>\$</u>	<u>\$</u>

The Company has historically experienced significant operating losses and operates in an industry subject to rapid technological changes. Therefore, the Company believed that there was sufficient uncertainty regarding its 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 29, 2002.

At March 28, 2003, the Company projects taxable income for fiscal 2004 and 2005. According to the Company's projected taxable income, the Company anticipates tax benefits from utilization of net operating loss carryforwards of approximately \$7.3 million each in fiscal 2004 and 2005. A valuation allowance of \$4.2 million for deferred tax asset was released for the amount of net operating loss carryforwards after tax expected to be utilized in fiscal 2004 and 2005.

At March 28, 2003 the Company had net operating loss carryforwards available to reduce future taxable income through 2022 for federal tax purposes of approximately \$33.9 million. 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 \$2.2 million and \$109,000, respectively. Deferred tax assets related to stock option deductions for which a full valuation allowance has been established are approximately \$2.5 million. To the extent that net operating loss carry-forwards are recognized related to stock option deductions, the resulting benefits will be credited to shareholder equity.

As a result of a change in ownership (for tax purposes) which occurred in fiscal 1991, 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 net operating loss carryforwards and the use of approximately \$550,000 of federal and state tax credit carryforwards.

10. Geographic Information

The Company's export sales were \$6.6 million, \$8.0 million and \$6.5 million for fiscal 2003, 2002 and 2001, respectively. Sales to Europe were \$4.4 million, \$6.4 million and \$5.1 million in fiscal 2003, 2002 and 2001, respectively, with the remainder of export sales to Asia and South America. All of the Company's assets are located in the United States.

Table of Contents**SCHEDULE II****CHOLESTECH CORPORATION****VALUATION AND QUALIFYING ACCOUNTS**

	Balance at Beginning of Period	Additions to Costs & Expenses	Deductions	Balance at End of Period
Fiscal Year Ended March 30, 2001				
Allowance for doubtful accounts	\$ 137,000	\$ 224,000	\$ 270,000	\$ 91,000
Allowance for sales returns	83,000			83,000
Inventory reserve	179,000	107,000	60,000	226,000
Fiscal Year Ended March 29, 2002				
Allowance for doubtful accounts	\$ 91,000	\$ 163,000	\$ 135,000	\$ 119,000
Allowance for sales returns	83,000		58,000	25,000
Inventory reserve	226,000	30,000	175,000	81,000
Fiscal Year Ended March 28, 2003				
Allowance for doubtful accounts	\$ 119,000	\$ 59,000	\$ 2,000	\$ 176,000
Allowance for sales returns	25,000		20,000	5,000
Inventory reserve	81,000	92,000		173,000

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.

Table of Contents**EXHIBIT INDEX**

3.1(1)	Restated Articles of Incorporation of Registrant
3.2(2)	Bylaws of Registrant, as amended to date
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, as amended, and forms of agreements thereto
10.3(2)	Standard Industrial Lease Agreement between Registrant and Sunlife Assurance Company of Canada dated October 22, 1989
10.3.1(5)	First Amendment to Standard Industrial Lease Agreement between Registrant and Sunlife Assurance Company of Canada dated April 1995
10.4(2)	Form of Indemnification Agreement between Registrant and its officers and its directors
10.17.1(6)	Letter Agreement effective December 20, 1996 by and between Wells Fargo Bank and Registrant
10.17.2(6)	Revolving Line of Credit Note effective December 20, 1996 by and between Wells Fargo Bank and Registrant
10.17.3(6)	General Pledge Agreement effective December 20, 1996 by and between Wells Fargo Bank and Registrant
10.17.4(7)	Revolving Line of Credit Note effective November 30, 1997 by and between Wells Fargo Bank and Registrant
10.17.5(8)	Revolving Line of Credit Note effective November 30, 1998 by and between Wells Fargo Bank and Registrant
10.17.6(9)	Revolving Line of Credit Note Effective November 30, 1999 by and between Wells Fargo Bank and Registrant
10.17.7(10)	Revolving Line of Credit Note effective May 1, 2000 by and between Wells Fargo Bank and Registrant
10.17.8(11)	Revolving Line of Credit Note effective September 10, 2001 by and between Wells Fargo Bank and Registrant
10.20(12)	1997 Stock Incentive Program, as amended, and form of agreement thereto
10.21(13)	1999 Nonstatutory Stock Option Plan, as amended, and form of agreement thereto
10.24(17)	Employment Agreement between Registrant and David A. Gyorke dated July 6, 2000
10.25(10)	Employment Agreement between Registrant and Thomas E. Worthy dated August 6, 1999
10.26(10)	Employment Agreement between Registrant and Terry L. Wassmann dated March 28, 2000
10.28(10)	Employment Agreement between Registrant and Timothy I. Still dated October 6, 1999
10.29(11)	2000 Stock Incentive Program, as amended, and form of agreement thereto
10.32(14)	Employment Agreement between Registrant and William W. Burke dated March 14, 2001
10.33(14)	Lease Agreement between Registrant and Terradev Jefferson LLC dated July 28, 2000
10.34(14)	Second Amendment to Standard Industrial Lease Agreement between Registrant and Sunlife Assurance Company of Canada dated March 17, 1995
10.35(14)	Third Amendment to Standard Industrial Lease Agreement between Registrant and Sunlife Assurance Company of Canada dated January 27, 1997

Table of Contents

10.36(14)	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
10.37(11)	Lease Agreement between Registrant and the BIV Group dated July 23, 2001
10.38(15)	2002 Employee Stock Purchase Plan and form of agreement thereto
10.39(16)	Stock Purchase Agreement dated December 23, 2002 between Registrant, WellCheck Inc. and ImpactHealth.com, Inc.
10.40	Amended and Restated Severance Arrangement between Registrant and Warren E. Pinckert II dated June 14, 2001
10.40.1	First Amendment to Amended and Restated Severance Arrangement between Registrant and Warren E. Pinckert II dated March 27, 2003
10.41	Change of Control Severance Agreement between Registrant and Warren E. Pinckert II dated June 14, 2001
10.41.1	First Amendment to Change of Control Severance Agreement between Registrant and Warren E. Pinckert II dated January 23, 2003
10.42	Severance Agreement between Registrant and William W. Burke dated July 17, 2001
10.43	Change of Control Severance Agreement between Registrant and William W. Burke dated July 21, 2001
10.43.1	First Amendment to Change of Control Severance Agreement between Registrant and William W. Burke dated January 23, 2003
10.44	Severance Agreement between Registrant and David A. Gyorke dated July 25, 2001
10.45	Severance Agreement between Registrant and Timothy I. Still dated July 19, 2001
10.46	Severance Agreement between Registrant and Terry L. Wassmann dated July 17, 2001
10.46.1	First Amendment to Severance Agreement between Registrant and Terry L. Wassmann dated January 23, 2003
10.47	Change of Control Severance Agreement between Registrant and Terry L. Wassmann dated January 23, 2003
10.47.1	First Amendment to Change of Control Severance Agreement between Registrant and Terry L. Wassmann dated January 23, 2003
10.48	Severance Agreement between Registrant and Thomas E. Worthy dated July 19, 2001
10.49	Transition Agreement between Registrant and Robert J. Dominici dated December 18, 2002
10.50	Employment Agreement between Registrant and Donald P. Wood dated March 31, 2003
10.51	Severance Agreement between Registrant and Donald P. Wood dated April 1, 2003
23.1	Consent of Independent Accountants
24.1	Power of Attorney (see page 60)
99.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(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 Quarterly Report on Form 10-Q for the quarter ended June 30, 1995.

Table of Contents

- (6) Incorporated by reference to exhibits filed with Registrant s Quarterly Report on Form 10-Q for the quarter ended December 27, 1996.
- (7) Incorporated by reference to exhibits filed with Registrant s Quarterly Report on Form 10-Q for the quarter ended December 26, 1997.
- (8) Incorporated by reference to exhibits filed with Registrant s Quarterly Report on Form 10-Q for the quarter ended December 25, 1998.
- (9) Incorporated by reference to exhibits filed with Registrant s Quarterly Report on Form 10-Q for the quarter ended December 24, 1999.
- (10) Incorporated by reference to exhibits filed with Registrant s Annual Report on Form 10-K for the fiscal year ended March 31, 2000.
- (11) Incorporated by reference to exhibits filed with Registrant s Quarterly Report on Form 10-Q for the quarter ended September 28, 2001.
- (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 (333-44980) as declared effective by the Securities and Exchange Commission on August 31, 2000.
- (14) Incorporated by reference to exhibits filed with Registrant s Annual Report on Form 10-K for the fiscal year ended March 30, 2001.
- (15) Incorporated by reference to exhibits filed with Registrant s Registration Statement on Form S-8 (No. 333-98143) as declared effective by the Securities and Exchange Commission on August 15, 2002.
- (16) Incorporated by reference to exhibits filed with Registrant s Report on Form 8-K (File No. 000-20198) filed with the Securities and Exchange Commission on January 6, 2003.
- (17) Incorporated by reference to exhibits filed with Registrant s Annual Report on Form 10-K for the fiscal year ended March 29, 2002.