

CHOLESTECH CORPORATION

Form 10-K

June 08, 2004

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**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 26, 2004  
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

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**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**

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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 26, 2003 as reported on the NASDAQ National Market, was approximately \$80,034,000. 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.

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As of May 28, 2004, the registrant had outstanding 14,184,571 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 2004 Annual Meeting of Shareholders to be held August 18, 2004.

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## CHOLESTECH CORPORATION

ANNUAL REPORT ON FORM 10-K  
For The Fiscal Year Ended March 26, 2004

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**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 43 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.

**ITEM 1. BUSINESS**

**Overview**

We are a leading provider of diagnostic tools and information for immediate risk assessment and therapeutic monitoring of heart disease and diabetes. We currently manufacture the LDX® System (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. In fiscal year 2004, revenue from sales of the LDX Analyzer and single use test cassettes represented over 90% of our revenue.

We also market and distribute the GDX™ System (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 A1C ( 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.

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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 by the U. S. Census Bureau that approximately 44 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.

We specifically target our products at markets outside of traditional hospital or clinical laboratories through our worldwide network of over 85 distributors. Our primary market is the physician office laboratory market, which consists of approximately 100,000 sites operated by physicians or groups of physicians that are registered with the Centers for Medicare & Medicaid Services ( CMS ), approximately 49,000 of which are registered to perform only tests that have been waived under CLIA. According to CMS, the number of CLIA waived physician office laboratories has increased 28% since 1998. In fiscal year 2004, sales of our products to the physician office laboratory market represented 54% of our revenue.

We also sell our products to the health promotion market, which includes a variety of venues 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. In fiscal year 2004, sales of our products to the health promotion market represented 32% of our revenue. Sales of our products to international markets represented 14% of revenue in fiscal year 2004. While a majority of such sales are in Europe, we are expanding into Asia, the Middle East and Latin America. See Note 12 of the consolidated financial statements for details on our international revenue.

Providing rapid service to our customers is one of the fundamentals of our business. Generally we fulfill our customers orders within two business days of the placement of an order, resulting in no material backlog as of March 26, 2004. Although there are certain months of the year in which testing for cholesterol typically increases, such as September which is National Cholesterol Month and February which is National Heart Month, historically we have not experienced fluctuations in sales of our products due to seasonality.

We plan to leverage our worldwide installed base of diagnostic systems in our customers locations and current LDX product platform by introducing new test cassettes. In addition, we plan to leverage our distribution capabilities by adding new technology platforms, such as our recently announced market development and product distribution agreement involving a novel and proprietary system for addressing endothelial dysfunction. We believe that this strategy, combined with the enactment of Medicare coverage for cholesterol and diabetes screening in the calendar year 2005, a continued emphasis by major pharmaceutical companies on obtaining over-the-counter status for certain statin drugs and the ongoing efforts by pharmaceutical companies to promote awareness of both the risk factors and the importance of screening and monitoring related to heart disease and diabetes, will position our company to capitalize on attractive long-term growth opportunities.

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### **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 cardiovascular disease, which remains the leading cause of death in the United States and kills more people than the next five diseases combined. Heart disease is also the leading cause of death among diabetics.

In 2002, the estimated cost in the United States of coronary heart disease and diabetes was \$245 billion.

The American Heart Association estimates that more than 64 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, which has a death rate from heart disease which is two to four times higher than for those who do not have diabetes.

Based on evidence from scientific studies, the National Cholesterol Education Program ( NCEP ) expert panel and the National Institutes of Health ( NIH ) issued guidelines in May 2001 which are expected to substantially increase the number of Americans being treated for high cholesterol. Numerous research studies substantiate that reducing high cholesterol levels reduces the risk of a coronary event by 31%.

Based on the NIH guidelines, approximately 201 million Americans should be screened or monitored 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 18 million people in the United States, over a third of whom have not yet been identified as being diabetic. Additionally, 41 million Americans require treatment for prevention of diabetes and 97 million should be screened or monitored for diabetes risk based on data from American Diabetes Association and Health and Human Services guidelines.

### **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:

*Expand Testing Technology to Leverage Our Installed Base.* 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

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aspartate aminotransferase ( AST ), high sensitivity C-Reactive Protein ( hs-CRP ) and lipid profile/alanine aminotransferase ( Lipid/ALT ).

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

*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 85 distributors. We continue to implement marketing and related programs to increase awareness of the advantages of the LDX System among healthcare providers and third party payors.

*Expand Sales Force and Distribution Relationships.* We intend to augment our sales and marketing efforts by increasing our sales force as well as our worldwide network of over 85 distributors.

*Expand Manufacturing Capabilities and Efficiencies.* We continue to expand our manufacturing capacity for the single-use cassettes. Additionally, we plan to continue to introduce improvements into our processes to enhance our manufacturing operations, including quality, throughput, yields and efficiencies.

**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.

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 GDX System is an A1C testing system that is CLIA waived and is used to measure A1C in less than five minutes by 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.

Our research and development expenses were \$3.2 million, \$2.7 million and \$2.2 million for fiscal year 2004, fiscal year 2003 and fiscal year 2002, respectively.

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*Overview of the Cholestech LDX System*

The LDX System is an easy to use, multi-analyte testing system, waived under CLIA, 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 implemented 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*

Revenue from the LDX Analyzer represented 8%, 9% and 11% of total revenue in fiscal year 2004, fiscal year 2003 and fiscal year 2002, respectively. 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.

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.



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*Cassette Products*

Revenue from cassette products represented 81%, 79% and 82% of total revenue in fiscal year 2004, fiscal year 2003 and fiscal year 2002, respectively. Our product 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 comes into contact with 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, waived under CLIA, 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. 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 transferred to a printer, computer or computer network. The GDX Analyzer is certified by the National Glycohemoglobin Standardization Program. The GDX Analyzer, along with accessories, comprises a GDX System and currently has a domestic list price of \$895.

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*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.

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

Product	Regulatory Status(1)
<b>Instrument</b>	
LDX Analyzer	FDA cleared; CLIA waived
GDX Analyzer	FDA cleared, CLIA waived
Endo-Pat 2000	FDA cleared
<b>Cassette Products</b>	
<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)	FDA cleared
High Sensitivity C-Reactive Protein (hs-CRP)	
Lipid Profile/ Alanine Aminotransferase (Lipid/ ALT)	No regulatory filing required
<i>In Feasibility Studies(3)</i>	
Total Bilirubin (Tbil)	Not filed or applied
Alkaline Phosphate (ALP)	Not filed or applied
Gamma Glutamyl Transferase (GGT)	Not filed or applied
Creatine Kinase (CK)	Not filed or applied
Blood Urea Nitrogen (BUN)	Not filed or applied
Creatinine	Not filed or applied
Potassium (K)	Not filed or applied
Uric Acid	Not filed or applied
Direct Low Density Lipoproteins (LDL)	Not filed or applied
Hemoglobin A1c (A1C)	Not filed or applied
<b>Cartridge Product</b>	
Hemoglobin A1c (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

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

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

### *Current Cassette 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.

*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.

*Alanine Aminotransferase.* Patients undergoing certain drug therapies must be monitored for increases in certain enzymes that are associated with liver damage. The

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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.

A1C. Hemoglobin A1c ( 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.

*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. We received 510(k) clearance from the FDA for our AST test in September 2003 and we have applied for a CLIA waiver for this product. The availability of an aspartate aminotransferase ( AST ) test in conjunction with our ALT test would allow healthcare providers to monitor both the impact of and potential adverse side effects on the liver from lipid lowering and diabetic therapies.

*High Sensitivity C-Reactive Protein.* The high sensitivity C-Reactive Protein ( hs-CRP ) test measures, by immunoassay, the amount of HS-CRP present in a patient sample. Recent research has demonstrated that HS-CRP is a marker of coronary artery inflammation that is an early step in the development of a heart attack. Studies have shown that hs-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.

*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.

*Hepatic Panel*

*Total Bilirubin.* The total bilirubin test is a liver function test that is helpful in the differentiation of the cause of jaundice.

*Alkaline Phosphatase.* Alkaline phosphatase is a group of enzymes that are active at an alkaline pH. Alkaline phosphatase activity is highest in the liver, bone, intestine and

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kidney and is a useful test of liver function. Measurement of alkaline phosphatase in the blood can differentiate hepatobiliary disease from osteogenic bone disease.

*Gamma Glutamyl Transferase.* Gamma glutamyl transferase ( GGT ) is found in the kidney and liver. Blood GGT is generally elevated as a result of liver disease and is elevated earlier than other liver enzymes in certain liver diseases.

*Drug Monitoring Panel*

*Creatine Kinase.* Creatine kinase ( CK ) is an enzyme with high levels of enzyme activity in skeletal muscle. Measurement of CK in patients on statin drug therapy is useful for monitoring for damage to skeletal muscle, a rare side effect of statin therapy.

*Renal Panel*

*Blood Urea Nitrogen.* Blood urea nitrogen ( BUN ) is commonly used as an aid in monitoring kidney (renal) function. BUN elevations occur in chronic renal disease, as well as in urinary tract obstruction. BUN is also useful in monitoring hemodialysis and other therapies.

*Creatinine.* Creatinine is another measure of renal function and is usually tested for in combination with BUN. In addition, creatinine is used as an indication of renal blood flow, which may be reduced due to congestive heart failure or dehydration. Low levels of creatinine may also result from decreased hepatic function in advanced liver disease.

*Potassium.* Potassium is the primary indication of intracellular fluid and maintenance of normal potassium levels is essential to the life of the cells. Potassium levels are regulated by the kidneys and measurement of potassium in blood is an indicator of renal function.

*Uric Acid.* Uric acid is a metabolic product of the oxidation of purines. Measurement of uric acid is useful for diagnosis and monitoring for chronic renal failure when there is a progressive increase in the plasma levels of uric acid.

*Individual Test Cassettes*

*Direct Low Density Lipoproteins.* The direct low density lipoproteins ( LDL ) cholesterol test permits the direct measurement of LDL cholesterol in a patient sample. The calculation of LDL cholesterol is subject to a number of limitations, including the need for a fasting sample.

*Hemoglobin A1C.* 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.

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*Other Platforms*

*Vascular Endothelial Dysfunction.* The Endo-Pat 2000 is a non-invasive device that is used as a diagnostic aid in the detection of coronary artery endothelial dysfunction. Vascular disease experts recognize endothelial dysfunction as an early stage in the development of atherosclerosis and potentially fatal outcomes such as heart attack, aneurysms, and stroke. An endothelial dysfunction assessment using the Endo-Pat 2000 can be completed in a 20-minute office visit, enabling physicians to provide immediate treatment and feedback in-person with the patient.

**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 related companies to enhance our business strategy in the management of chronic diseases. Our current strategic relationships are described below.

*Distribution*

We have non-exclusive distribution agreements to market, sell and distribute our products to healthcare providers in the United States, Europe, Latin America and Asia. We believe our partnerships will further our access to medical, occupational health and other health care professionals who seek effective in-office diagnostic and therapeutic monitoring tools for cholesterol and diabetes management. Significant distributors of our product include: Cardinal Health, Inc., Edwards Medical Supply, Fisher Scientific International, Inc., McKesson Corporation, Physician Sales and Service, Inc. and Henry Schein, Inc.

*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, a testing services business which was formally 100% owned by us. 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.

*Itamar Medical*

In April 2004, we signed a market development and product distribution agreement with Itamar Medical Limited ( Itamar ), involving a novel and proprietary system for assessing vascular endothelial dysfunction. Vascular disease experts recognize endothelial dysfunction as an early stage in the development of atherosclerosis.

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### *Marketing Programs*

Our LDX System continues to be utilized in a number of regionally based marketing programs in the United States, including healthcare industry conventions. Our international sales and marketing team continues to work with selected global pharmaceutical companies in connection with country specific marketing programs. Pharmaceutical companies, such as AstraZeneca PLC and Pfizer Inc., utilize our LDX System in connection with such programs. Pfizer has renewed its agreement with ImpactHealth to provide cholesterol testing services at selected healthcare industry conventions in 2004.

### **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 distribution partnering and marketing activities.

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. Over the past year, we expanded the number of domestic sales and field technical service associates. We plan to dedicate a significant portion of our 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 increase 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, Cardinal Health, Inc., Fisher Scientific International, Inc., McKesson Corporation, Physician Sales and Service Inc. and Henry Schein, Inc., which together have more than 2,500 sales professionals who focus on the United States physician office laboratory market. We have also retained more than 35 regional distributors in the United States. In addition, we and our distributors focus 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 who conduct diagnostic screening for cholesterol and related lipid levels and diabetes.

*International.* Our international distribution strategy is to penetrate targeted geographical markets by selling directly to distributors in those markets. We have entered into non-exclusive agreements with approximately 30 foreign distributors to distribute our products and cassettes primarily in Europe, Asia and South America.



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### **Competition**

The diagnostic products 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.

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, including Polymer Technology Systems, Inc., are currently making or developing products that compete or will compete with us. We believe we currently have a competitive advantage due to (i) 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; (ii) our ALT test, which is the only ALT test waived under CLIA by the FDA and enables physicians to monitor the potential side effects on the liver from cholesterol lowering drugs and other medications; (iii) the improving breadth of the CLIA waived tests that we can offer our installed base and (iv) our network of over 85 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 waiver under CLIA.

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, the capability 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 69,000 square foot facility 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 suppliers and are shipped to us for final assembly and quality assurance. Our manufacturing process for the LDX Analyzer consists primarily of assembly, testing,

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inspection and packaging. Testing consists of a burn-in period, functional tests and integrated system testing using specially produced test cassettes. Our manufacturing process complies with FDA Quality System Requirements, ISO 9001 and TÜV GS Mark 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 suppliers and convert these raw materials, using proprietary processes, into single-use test cassettes. We believe our proprietary processes and custom designed equipment are important components of our cassette manufacturing operations. We have developed core manufacturing technologies, processes and production machinery, including membrane lamination and welding, discrete membrane impregnation, on-line calibration and software control of the manufacturing process. The overall manufacturing process meets FDA Quality System Requirements and in-vitro diagnostic directive, including in process and final quality assurance testing. The majority our cassette production is currently on our high volume manufacturing line. We use a second manufacturing line for research and development purposes and production overflow.

*Raw Materials and Quality Assurance.* Suppliers provide us with the subassemblies, components and raw materials necessary for the manufacturing 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 assurance 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

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implement alternative approaches could have a material adverse effect on our business, financial condition and results of operations.

In December 2003, we and Roche Diagnostics signed a settlement agreement and a license agreement which settled all existing patent litigation between us on a worldwide basis. The settlement included a lump sum payment by us to Roche in the amount of \$7.0 million (which was paid in December 2003) and the dismissal of all patent claims between us. As part of the settlement, we agreed to pay Roche an ongoing royalty and Roche granted an irrevocable, non-exclusive, worldwide license to us for its patents related to HDL cholesterol. In addition, the parties have also agreed upon a mechanism for the resolution of future patent infringement disputes. We believe that any such dispute resolution will confirm that our HDL cholesterol test cassette, currently under development, does not infringe upon Roche's patents. If however, upon the resolution of any dispute, it is ultimately determined that our new HDL cholesterol test cassette is covered by Roche's patents, we will pay Roche the same ongoing royalty.

There can be no assurance that patent infringement claims will not be asserted against us 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.

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 "FDCA"), 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

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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 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

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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 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

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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. For example, in December 2003, provisions for cholesterol and diabetes screening, which are expected to be implemented in January 2005, were included in the federal Prescription Drug and Medicare Improvement Act of 2003. 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 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

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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.

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 26, 2004, we employed 199 full-time associates. There were 85 employees in manufacturing, 55 employees in sales and marketing, 32 employees in administration and 27 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.

**Table of Contents****Executive Officers**

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

Name	Age	Position
Warren E. Pinckert II	60	President, Chief Executive Officer and Director
William W. Burke	45	Vice President of Finance, Chief Financial Officer, Treasurer and Secretary
Kenneth F. Miller	48	Vice President of Sales and Marketing
Terry L. Wassmann	57	Vice President of Human Resources
Donald P. Wood	52	Vice President of Operations
Thomas E. Worthy	62	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 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.

*Kenneth F. Miller* has served as our Vice President of Sales and Marketing since June 2004. Before joining Cholestech, Mr. Miller served as the Chief Operating Officer at R2 Technology Inc. from July 2002 to March 2004. He also served as R2 Technology's Chief Marketing Officer from June 2000 to June 2002. Prior to joining R2 Technology, Mr. Miller served as Chief Operating Officer of LiquidBorclens Inc. from October 1999 to May 2000 and Vice President of Sales of Alaris Medical Inc. from April 1997 to October 1999. Mr. Miller holds a bachelor of Science degree in Chemistry, Zoology, and Physiology from Rutgers University and a Masters of Business Administration degree from Fairleigh Dickinson University.

*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



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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 Operations for BioChem Pharma Inc. from July 1994 to October 1995 and Mr. Wood held numerous positions within operations for Serono Diagnostics Inc. 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.

**Available Information**

We are subject to the reporting requirements under the Securities Exchange Act of 1934. Consequently, we are required to file reports and information with the Securities and Exchange Commission (SEC), including reports on the following forms: annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. These reports and other information concerning our company may be accessed through the SEC's website at <http://www.sec.gov>. The public may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 450 Fifth Street, NW, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330.

You may also find on our website at <http://www.cholestech.com> electronic copies of our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934. Such filings are placed on our website as soon as reasonably possible after they are filed with the SEC. The contents of our website are not incorporated by reference in this Annual Report on Form 10-K.

**ITEM 2: PROPERTIES**

Our offices are located in a leased 69,000 square foot facility in Hayward, California. Our facilities contain approximately 10,000 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

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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. B/02/00044), 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. At the introductory hearing on April 1, 2003, the case was sent to the general docket and there have been no further developments. We believe this claim is without merit and intend to continue to defend the claim vigorously.

On March 14, 2003, we initiated trademark infringement proceedings against Euromedix before the President of the Commercial Court in Leuven, Belgium (No. BRK/03/00017), seeking in principle an order (i) to prohibit Euromedix from selling, stocking, importing, exporting or promoting in the European Economic Area (EEA) products that violate our trademarks, under a penalty of 10,000 Euros for each LDX-Analyzer sold, a penalty of 1,000 Euros for each cassette sold contrary to the prohibition and a 25,000 Euros penalty for each publicity of advertisement for such products; (ii) to prohibit Euromedix from using certain slogans and phrases, in combination with products associated with certain of our trademarks, in trade documents or other announcements, under a penalty of 25,000 Euros for each document used contrary to this prohibition; and (iii) to order the destruction of the inventory of products held by Euromedix that violate our trademarks, which have been imported into the EEA without our permission.

A hearing was held on April 29, 2003 regarding certain procedural issues. In a judgment rendered on May 27, 2003, the Judge of Seizures of the Court of First Instance referred the complaint to the Constitutional Court before rendering a final decision. The Judge of Seizures asked the Constitutional Court to render an opinion regarding certain constitutional issues related to the trademark infringement arguments we raised at the hearing. Hearings in the Constitutional Court were held on July 8, 2003 and September 9, 2003. On March 24, 2004, the Constitutional Court issued its judgment which supported our claims. We are currently taking steps to continue the proceedings before the Judge of Seizures and the Commercial Court.

On March 26, 2004, a putative class action lawsuit captioned *Northshore Dermatology Center, S.C. v. Cholestech Corporation, and Does 1-10*, Case No. 04CH05342, was filed in the Circuit Court of Cook County, Illinois. We were served with the complaint and summons on March 31, 2004. The complaint alleges that we violated the federal Telephone Consumer Protection Act and various Illinois state laws by sending unsolicited advertisements via facsimile transmission to residents of Illinois. The complaint seeks class certification and statutory damages of \$500 to \$1,500 on behalf of a class that would include all residents of Illinois who received an unsolicited facsimile advertisement from us. To date, we have not responded to the complaint. We believe this claim is without merit and intend to continue to defend the claim vigorously. The ultimate outcome of this matter cannot presently be determined. The liability that could potentially result from a negative outcome cannot be reasonably estimated but could be material to the financial position or results of operations of our Company.

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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. 03-CV-0303-LJM-WTL), seeking a preliminary and permanent injunction, damages and attorneys fees for patent infringement. We were served with the suit on June 30, 2003. The complaint alleges that we are violating three Roche U.S. patents for HDL. On July 21, 2003, we filed an answer and counter claim with the U.S. District Court for the Southern District of Indiana.

On December 19, 2003, we entered into a settlement agreement and license agreement with Roche Diagnostics Corporation and Roche Diagnostics GmbH in connection with ongoing patent infringement litigation. The settlement, which serves as the basis for the dismissal of all patent litigation between us and Roche on a worldwide basis, included a lump sum payment by us to Roche in the amount of \$7 million payment, which we made on December 30, 2003. In addition, Roche agreed to grant an irrevocable, non-exclusive, worldwide license to us for its patents related to HDL cholesterol. As a part of this settlement, we will pay Roche an ongoing royalty that will be applied to only the HDL portion of cholesterol test cassettes we sell. Additionally the settlement agreement provides a mechanism for resolving any future patent infringement disputes. We believe that any such dispute resolution will confirm that our new HDL cholesterol test cassette, currently under development, does not infringe Roche's patents. If however, upon the resolution of any such dispute it is ultimately determined that our new HDL cholesterol test cassette is covered by Roche's patents, then we will pay the same ongoing royalty. As a result of the settlement, the parties have filed motions to dismiss the proceedings in the United States and the proceedings described below in Germany, Belgium, Switzerland and Austria.

On December 23, 1999, 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.

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. On January 10, 2003, we appealed this ruling with the Appeal Court in Dusseldorf.

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.

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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.

We are also 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 financial statements.

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

None.

**PART II**

ITEM 5: MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock is quoted on the NASDAQ National Market under the symbol CTEC. On March 26, 2004, the last reported sale price for our common stock on the NASDAQ National Market was \$8.55 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
<b>FISCAL YEAR 2003</b>		
First Quarter	\$20.05	\$9.25
Second Quarter	15.30	8.55
Third Quarter	11.45	4.35
Fourth Quarter	8.80	6.00
<b>FISCAL YEAR 2004</b>		
First Quarter	\$12.89	\$7.28
Second Quarter	11.11	7.30
Third Quarter	9.31	6.20
Fourth Quarter	9.39	6.72

As of March 26, 2004, there were 14,094,994 shares of our common stock issued and outstanding and held by approximately 170 holders of record. We estimate that there are approximately 4,700 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

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the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future.

**Equity Compensation Plans**

The information required by this item regarding equity compensation plans is incorporated by reference under the section entitled *Executive Compensation and Other Matters* contained in our proxy statement for our 2004 annual meeting of shareholders.

**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 26, 2004, March 28, 2003 and March 29, 2002 and the selected consolidated balance sheet data as of March 26, 2004 and March 28, 2003 are derived from, and qualified by reference to, the audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. 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 30, 2001 and March 31, 2000 and the consolidated balance sheet data as of March 29, 2002, March 30, 2001 and March 31, 2000 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.

Year Ended March 31,(1)	2004	2003	2002	2001	2000
<i>(in thousands, except per share data)</i>					
<b>Consolidated Statement of Operations Data:</b>					
Revenue	\$ 52,376	\$48,541	\$41,747	\$32,489	\$26,806
Cost of revenue	23,180	20,424	17,040	14,054	10,862
Gross profit	<u>29,196</u>	<u>28,117</u>	<u>24,707</u>	<u>18,435</u>	<u>15,944</u>
Operating expenses:					
Sales and marketing	12,654	11,737	9,241	8,287	6,831
Research and development	3,159	2,722	2,201	2,195	2,412
General and administrative	8,153	7,008	6,447	4,293	2,370
Other operating costs	250				
Litigation and other related	7,786	307	126	1,311	219
Total operating expenses	<u>32,002</u>	<u>21,774</u>	<u>18,015</u>	<u>16,086</u>	<u>11,832</u>
Income (loss) from operations	(2,806)	6,343	6,692	2,349	4,112
Interest and other income, net	278	438	449	655	805
Income (loss) before taxes	(2,528)	6,781	7,141	3,004	4,917
Provision (benefit) for income taxes(2)	<u>(11,201)</u>	<u>(3,934)</u>	<u>289</u>	<u>224</u>	<u>181</u>

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Year Ended March 31,(1)	2004	2003	2002	2001	2000
<i>(in thousands, except per share data)</i>					
Income from continuing operations	8,673	10,715	6,852	2,780	4,736
Gain (loss) from discontinued operations	34	(1,377)	(1,302)	(5,386)	(1,604)
Loss from sale of discontinued operations		(4,445)			
Net income (loss)	\$ 8,707	\$ 4,893	\$ 5,550	\$ (2,606)	\$ 3,132
Income from continuing operations per share:					
Basic	\$ 0.62	\$ 0.79	\$ 0.54	\$ 0.23	\$ 0.41
Diluted	\$ 0.61	\$ 0.76	\$ 0.50	\$ 0.22	\$ 0.40
Loss from discontinued operations per share:					
Basic	\$ 0.01	\$ (0.43)	\$ (0.10)	\$ (0.45)	\$ (0.14)
Diluted	\$ 0.00	\$ (0.41)	\$ (0.10)	\$ (0.43)	\$ (0.14)
Net income (loss) per share:					
Basic	\$ 0.63	\$ 0.36	\$ 0.44	\$ (0.22)	\$ 0.27
Diluted	\$ 0.61	\$ 0.35	\$ 0.40	\$ (0.21)	\$ 0.26
Shares used to compute net income (loss) per share(3):					
Basic	13,922	13,551	12,658	12,046	11,724
Diluted	14,235	14,077	13,730	12,416	11,920

Year Ended March 31,(1)	2004	2003	2002	2001	2000
<i>(in thousands)</i>					
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and marketable securities and long term investments	\$ 23,602	\$ 26,081	\$ 22,107	\$ 12,365	\$ 13,741
Working capital	23,986	22,579	20,848	10,254	11,522
Total assets	63,230	52,012	42,751	30,742	32,218
Accumulated deficit	(27,157)	(37,587)	(42,480)	(48,030)	(45,424)
Shareholders equity	57,278	44,728	36,721	24,858	26,476

(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 year 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 ended March 26, 2004 as fiscal 2004, March 28, 2003 as fiscal year 2003, March 29, 2002 as fiscal year 2002, March 30, 2001 as fiscal year 2001 and the fiscal year ended March 31, 2000 as fiscal year 2000.

(2) Benefit for income taxes in fiscal years 2004 and 2003 includes a \$10.2 million and \$4.2 million, respectively, gain from a net deferred income tax benefit which resulted from the reversal of a portion of the valuation allowance previously established for deferred tax assets, primarily 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.

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

**Introduction**

Management's discussion and analysis of financial condition and results of operation, or MD&A, is provided as a supplement to the accompanying consolidated financial statements and footnotes contained in Item 15 of this report and provides an understanding of our results of operation, financial condition and changes in financial condition. This discussion contains forward-looking statements. These statements are based on our current expectations, assumptions, estimates and projections about our business and our industry, and involve known and unknown risks, uncertainties and other factors that may cause our or our industry's results, levels of activity, performance or achievement to be materially different from any future results, levels of activity, performance or achievements expressed or implied in or contemplated by the forward-looking statements. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of selected factors, including those set forth in this section. MD&A is organized as follows:

*Overview.* This section provides a general description and recent history of our business.

*Results of operations.* This section provides our analysis and outlook for the significant line items on our consolidated statements of operations.

*Liquidity and capital resources.* This section provides an analysis of our liquidity and cash flows, as well as a discussion of our commitments that existed as of March 26, 2004.

*Critical accounting policies.* This section discusses those accounting policies that both are considered important to our financial condition and results of operations, and require us to exercise subjective or complex judgments in their application. In addition, all of our significant accounting policies, including our critical accounting policies, are summarized in Note 1 to our consolidated financial statements.

*Recent accounting pronouncements.* This section describes the issuance and effects of new accounting pronouncements.

*Factors affecting future operating results.* This section discusses the most significant factors that could affect our future financial results. The factors discussed in this section are in addition to factors that may be described in the MD&A captions discussed above and elsewhere in this report.

**Overview**

We are a medical device company that develops, manufactures and markets products that perform diagnostic testing at sites outside of traditional hospital and clinical laboratories to assist in the assessment of the risk of heart disease, diabetes and certain liver diseases and in the monitoring of therapy to treat those diseases. Our products are sold worldwide. Our primary market is the physician laboratory market, which consists of approximately 99,000 sites that are registered with the Centers for Medicare & Medicaid Services (CMS), approximately 47,000 of which are registered to perform

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only tests that have been waived under CLIA. In fiscal year 2004, sales of our products to the physician office laboratory market represented 54% of our revenue.

Our corporate headquarters is located in Hayward, California. All of our manufacturing, research, regulatory and administrative activities are conducted at this location. We sell our products through a worldwide network of over 85 distributors. We have 23 regional sales managers who coordinate and work with our distribution partners to identify and promote sales of our products. We also employ 16 field technical service representatives who are responsible for field customer service and customer retention initiatives within our existing installed base of products.

*Recent Events*

We have experienced recent significant developments and are monitoring certain events that may have an impact on our company, including the following:

In June 2003, we announced that the German Patent and Trademark Office granted us a patent on a new method for the measurement of HDL cholesterol in human blood. We also filed patent applications for this new method in the United States and in Europe. We believe this new method will allow us to add new analytes to our disposable cassette format by eliminating certain interferences created using our original method.

In September 2003, we received 510(k) clearance from the FDA for our AST test. Upon receiving a CLIA waiver, we plan to market AST in conjunction with our ALT test, which will allow health care providers to monitor both the impact of and potential side effect on the liver from lipid-lowering and diabetic therapies.

In December 2003, we entered into a settlement agreement with Roche in connection with ongoing patent infringement litigation. The settlement, which serves as the basis for the dismissal of all patent litigation between us and Roche on a worldwide basis, included a lump sum payment by us to Roche in the amount of \$7 million. In addition, Roche agreed to grant an irrevocable, non-exclusive worldwide license to us for its patents related to HDL cholesterol. As part of this settlement we will pay Roche an ongoing royalty that will be applied to only the HDL portion of the cholesterol test cassettes we sell.

In December 2003, provisions for cholesterol and diabetes screening were included in the federal Prescription Drug and Medicare Improvement Act of 2003. Implementation of the bill is not expected before January 1, 2005. We believe that the addition of reimbursement for screening with benefit both our health promotion and physician office market segments as more individuals will be screened for high cholesterol and diabetes and ultimately treated by a physician.

In April 2004, we announced a market development and product distribution agreement involving a novel and proprietary system for assessing vascular endothelial dysfunction which will further broaden our portfolio of products that enable physicians to assess and monitor heart disease and diabetes. We will invest resources to support pre-launch market research and market development activities. We will also be responsible for the sale and installation of the Endo-Pat 2000 in early adopter sites to



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further promote recognition of the product and technology while assessing United States market development needs.

In fiscal year 2004, our revenue growth was driven primarily by sales of our products to the physician office laboratory market, which increased 17% over fiscal year 2003 and represented 54% of our total revenue, up from 50% of total revenue in fiscal year 2003. Given the expected continued growth in the number of CLIA waived physician office labs and in our estimated installed base of LDX Analyzers, we plan to devote a majority of our sales and marketing expenditures toward increasing both our penetration of this market and the utilization of single use disposable cassettes by our existing end user physician customers. In fiscal year 2005 we plan to begin promotional awareness programs and other initiatives to enhance the sales of our cassette products, which currently represent over 80% of our revenue. We expect that the introduction and continued development of products which can be used on our existing LDX platform or another platform that could be CLIA waived and can be sold to our installed base will be an important component of our growth strategy in the physician office laboratory market.

In conjunction with providing periodic promotional incentives to our distribution partners, we have historically offered small discounts to our standard distributor pricing for large unit volume purchases. Throughout fiscal year 2004, we experienced increasing demand by our distribution partners to offer such discounts toward the end of each quarter. We became concerned about the future impact on end-user pricing and the inefficiencies in our operations that resulted from month to month swings in shipping volume. As a result, beginning in the fourth quarter of fiscal year 2004, we decided to reduce the amount of product we sold to our distribution partners at a discount. In addition, we notified our distribution partners that in the future we will no longer offer any discounts of this type. We expect that this change in business practice will have a negative impact on our revenue in the first quarter of fiscal year 2005 and may have a similar impact in the second quarter of fiscal year 2005.

This strategic decision is part of a larger effort to improve the consistency and predictability of sales and the efficiency of our operations. Going forward, we believe we are in a position to capture sales from new products, strategic alliances, such as the market development and product distribution agreement with Itamar, and recent favorable legislative trends. As a result, we believe that focusing on distributor and installed base management will improve both the consistency and predictability of our sales effort and operating margins. In fiscal year 2005, we anticipate leveraging our installed base and current LDX platform with the introduction of three new single-use test cassette products.

**Results of Operations**

In the following discussion of our results of operations, results related to WellCheck have been classified as discontinued operations for fiscal year 2004 and reclassified as discontinued operations for fiscal year 2003 and fiscal year 2002. Additionally, for comparative purposes certain costs have been reclassified for fiscal years 2003 and 2002.

**Table of Contents****Comparison of Fiscal Years Ended March 26, 2004 and March 28, 2003**

Fiscal Year Ended	March 26, 2004		March 28, 2003		Amount of Increase (Decrease)	Percentage Increase (Decrease)
	Amount	% of sales	Amount	% of sales		
Revenue	\$ 52,376	100%	\$48,541	100%	\$ 3,835	8%
Cost of revenue	23,180	44	20,424	42	2,756	13
Gross profit	29,196	56	28,117	58	1,079	4
Operating expenses						
Sales and marketing	12,654	24	11,737	24	917	8
Research and development	3,159	6	2,722	6	437	16
General and administrative	8,153	16	7,008	14	1,145	16
Other operating costs	250				250	
Legal and other related	7,786	15	307	1	7,479	2,436
Total operating expenses	32,002	61	21,774	45	10,228	47
Income (loss) from operations	(2,806)	(5)	6,343	13	(9,149)	(144)
Interest and other income, net	278	1	438	1	(160)	(37)
Benefit for income taxes	(11,201)	(21)	(3,934)	(8)	(7,267)	185
Income from continuing operations	8,673	17	10,715	22	(2,042)	16
Gain (loss) from discontinued operations	34		(1,377)	(3)	1,411	102
Loss from sale of discontinued operations			(4,445)	(9)	4,445	100
Net income (loss)	\$ 8,707	17%	\$ 4,893	10%	\$ 3,814	78%

*Revenue.* Our total revenue increased 8% to \$52.4 million in fiscal year 2004 from \$48.5 million in fiscal year 2003 due primarily to increased revenue relating to the sale of single use test cassettes to the physician office laboratory market, which was attributable to the continued adoption of the ATP III guidelines for treatment of high cholesterol, the increased number of CLIA waived laboratories and increased growth in the use of statin drugs, all of which resulted in higher demand for our LDX Analyzer and single use test cassettes. Revenue from the physician office laboratory market in fiscal year 2004 increased 17% over fiscal year 2003. This increase was attributed to a 24% increase in unit volume for single-use test cassettes. We expect that the physician office laboratory market, which represented 54% of our revenue in fiscal year 2004, will continue to be our fastest growing market for the foreseeable future.

Revenue from the health promotion market decreased 6% in fiscal year 2004 due mainly to a 57% reduction in revenue for the GDX Analyzers and related single-use test cartridges. The comparative decline related to a single large sale of GDX Analyzers and other related products to a single customer during fiscal year 2003. In general, the health promotion market revenue also declined due to reduced promotional testing spending by pharmaceutical companies.

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International revenue increased 12% in fiscal year 2004 over fiscal year 2003. Revenue for single-use test cassettes increased 10% while the number of cassettes sold increased 13%. The increase was primarily due to the impact of promotional activities related to the launch by AstraZeneca PLC of its statin drug Crestor. International LDX Analyzer revenue decreased 12% in fiscal year 2004 due to lower promotional equipment spending by pharmaceutical companies. For the foreseeable future, we expect this market will continue to be effected by reduced promotional spending by pharmaceutical companies, primarily in Europe.

We believe revenue from the sale of the LDX Analyzer and single use test cassettes will continue to be the primary driver of our revenue growth during the next fiscal year. During the next fiscal year, we intend to focus more of our sales and marketing efforts on customer retention, with the goal of increasing the consumption of single use test cassettes for both current and new products by our installed base.

Revenue for the GDX Analyzer and single use test cartridges increased 15% in fiscal year 2004. The increase was primarily due to the benefit of a full year of revenue attributed to the product, which was launched in July 2002. In fiscal year 2005, we expect revenue from the GDX Analyzer and single use test cartridges to remain flat or decrease slightly.

*Cost of Revenue.* Cost of revenue includes direct labor, direct material, overhead and royalties. Our cost of revenue increased 13% to \$23.2 million in fiscal year 2004 from \$20.4 million in fiscal year 2003. The increase in cost of revenue related primarily to additional products shipped in support of the 8% increase in revenue in fiscal year 2004 over the prior fiscal year. Additionally, expenses associated with promotional programs tied to revenue increased in fiscal year 2004. Such expenses are expected to decrease from fiscal year 2004 levels during the next fiscal year due to additional controls to limit the scope of such programs. Factory spending increased 17% in fiscal year 2004 over fiscal year 2003, while unit production of single use test cassettes increased 21%. The increase in spending is related to royalty, material scrap, warranty and product testing costs. During fiscal year 2005, we anticipate factory spending will continue to increase at a rate lower than the increase in unit production as we improve manufacturing efficiency through increased production and improving control of spending and material variances.

We have licensed certain technology used in some of our products. One ongoing royalty agreement, which expires in calendar year 2006, requires us to pay a royalty of 2.0% on net sales of single use test cassettes. In December 2003, as part of a settlement agreement with Roche, we entered into another royalty agreement that will be applied to only the HDL portion of cholesterol test cassettes we sell. This new agreement was effective as of December 1, 2003 and expires on December 3, 2013. Total royalty expense was \$1.2 million in fiscal year 2004 and \$753,000 in fiscal year 2003 and was included in cost of revenue.

### *Operating Expenses*

*Sales and Marketing.* Our sales and marketing expenses include salaries, commissions, bonuses, expenses for outside services, marketing programs and travel expenses. Sales and marketing expenses increased 8% to \$12.7 million in fiscal year 2004 from \$11.7 million in fiscal year 2003. The increase in wages and related and travel reflects a full year impact of increased staffing related to providing additional technical service support to our installed base, which was expanded late in fiscal year 2003, and a severance accrual for our former Vice President of Sales and Marketing. The increase in outside

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services related to market research and expenses related to industry specific public relations initiatives. Product marketing expenses decreased primarily due to a reduction in free product samples and lower distributor relation expenses which declined due to our refocusing of sales activities towards more direct involvement by our sales force with the distributors.

*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 16% to \$3.2 million in fiscal year 2004 from \$2.7 million in fiscal year 2003. The increases in wages and related, outside services and development materials all relate to increased efforts to develop new test cassette products for use on our LDX Analyzer. We expect our costs for new product development to remain constant or increase slightly during fiscal year 2005 as we prepare new products for launch into the marketplace.

*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 16% to \$8.2 million in fiscal year 2004 from \$7.0 million in fiscal year 2003. The increase in shared facilities costs was attributable to a full year in the expanded space leased for our corporate offices in Hayward, California. Additionally, a larger percentage of shared facilities cost were included in the general and administrative expense in fiscal year 2004. We expect that the cost of shared facilities will remain constant or increase slightly during the next year. Insurance costs increased due to the additional policy premiums for directors and officers insurance. Outside service expenses increased due to larger expenditures for legal, accounting and consulting services during fiscal year 2004. As we continue to grow and expand into new jurisdictions and maintain profitability, we will continue to register with new state tax agencies. While the cost of taxes and other fees paid to state agencies have not been material, we have experienced a significant increase in accounting services expense related to the administration and filing of state income tax documentation. Additionally, we have required more outside professional services to meet the increasing cost of being a public company, including additional requirements of the Sarbanes-Oxley Act of 2002. We expect that fees for these outside services will remain constant or increase in the foreseeable future.

*Other Operating Costs.* In fiscal year 2004, other operating costs were \$250,000. We had no corresponding operating costs in fiscal year 2003. These costs related to the write-off of an option to purchase a patent, which we determined no longer had an economic value.

*Litigation and Other Related.* Our legal and related expenses included professional consulting fees, court related costs and other fees relating to Roche litigation. Legal and related expenses increased 2,436% to \$7.8 million in fiscal 2004 from \$307,000 in fiscal year 2003. These costs were related to our settlement with Roche in connection with ongoing patent infringement litigation. Pursuant to the settlement agreement, which serves as a basis for the dismissal of all patent litigation between us and Roche on a worldwide basis, we made a lump sum payment of \$7.0 million to Roche on December 30, 2003.

*Interest and Other Income, Net.* Interest income reflects income from the investment of cash balances and marketable securities, net of expenses. Interest income decreased 37% to \$278,000 in fiscal year 2004 from \$438,000 in fiscal 2003. The decline in interest income is attributable to lower yields on securities investments. Gains from the sale of marketable securities were \$121,000 during

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fiscal year 2004 compared to \$114,000 in fiscal year 2003. We expect income from securities investments to remain constant unless there is a material increase in the market yield on corporate bonds.

*Income Taxes.* The income tax benefit of \$11.2 million and \$3.9 million in fiscal years 2004 and 2003, respectively, is primarily related to the release of the valuation allowance previously established for our deferred tax assets. We released \$10.2 million of valuation allowance in fiscal year 2004 and \$4.2 million in fiscal year 2003. Based upon projected future operating performances, we currently believe that we will be able to fully utilize the value of our net operating loss carry forward ( NOL ) through reductions of taxes to be paid in future periods. During fiscal year 2003, the amount of valuation allowance we released was the estimated amount to be utilized during the next two fiscal years. As of March 26, 2004, we had NOL carryforwards of \$42.9 million available to reduce future taxable income for federal income tax purposes; however, we have fully consumed our NOL carryforwards for California state income tax purposes. Additionally, we had research and development and other tax credit carryforwards available of \$1.2 million to reduce income taxes for federal income tax purposes and research and development credits of \$281,000 for state income tax purposes.

As a result of a change in ownership (for tax purposes) which occurred in fiscal year 1991, we have an annual limitation of approximately \$1.5 million for federal and state income tax purposes on the combined use of approximately \$6.2 million of federal net operating loss carryforwards and the use of approximately \$550,000 of federal and state tax credit carryforwards.

*Discontinued Operations.* Discontinued operations include all revenue, cost of revenue, compensation, benefits, travel and other expenses related to the operations of WellCheck. Income from discontinued operations increased 102% to \$34,000 in fiscal year 2004 from a loss of \$1.4 million in fiscal year 2003. The increase in income from discontinued operations in fiscal year 2004 related mainly to TEAMS royalty revenue. In fiscal year 2003, the loss from discontinued operations related to the operations of WellCheck through December 23, 2003 when the business was sold. In fiscal year 2005, we anticipate that the gain from discontinued operations will be comparable to fiscal year 2004.

We will recognize contingent sales proceeds, pursuant to the terms of our sale of WellCheck, including the TEAMS royalty and performance remuneration, which will be recognized as earned as a component of discontinued operations.

*Loss on Sale of Discontinued Operations.* In fiscal year 2003, 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, goodwill, compensation expenses for staff, professional services, the termination of property leases and other liabilities in excess of the \$250,000 note receivable. We had no such charge in fiscal year 2004.

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

Fiscal Year Ended	March 28, 2003		March 29, 2002		Amount of Increase (Decrease)	Percentage Increase (Decrease)
	Amount	% of sales	Amount	% of sales		
Revenue	\$48,541	100%	\$41,747	100%	\$ 6,794	16%
Cost of revenue	20,424	42	17,040	41	3,384	20
Gross profit	28,117	58	24,707	59	3,410	14
Operating expenses						
Sales and marketing	11,737	24	9,241	22	2,496	27
Research and development	2,722	6	2,201	5	521	24
General and administrative	7,008	14	6,447	15	561	9
Legal and other related	307	1	126	1	181	144
Total operating expenses	21,774	45	18,015	43	3,759	21
Income from operations	6,343	13	6,692	16	(349)	(5)
Interest and other income, net	438	1	449	1	(11)	(2)
Provision (benefit) for income taxes	(3,934)	(8)	289	1	(4,223)	(1,461)
Income from continuing operations	10,715	22	6,852	16	3,863	56
Loss from discontinued operations	(1,377)	(3)	(1,302)	(3)	(75)	(6)
Loss from sale of discontinued operations	(4,445)	(9)			(4,445)	(100)
Net income (loss)	\$ 4,893	10%	\$ 5,550	13%	\$ (657)	(12)%

*Revenue.* Our total revenue increased 16% to \$48.5 million in fiscal year 2003 from \$41.7 million in fiscal year 2002. The increase in revenue primarily reflected an 11% increase in unit sales of single-use test cassettes. The physician office laboratory market unit sales of single-use test cassettes increased 29%. Additionally, health promotion market unit cassettes sales increased 7%. These increases were offset by decreased unit cassette sales in the international market, which declined 23% due to reduced promotional activities from large pharmaceutical companies. Domestic revenue represented 86% of total revenue in fiscal year 2003 compared to 81% in fiscal year 2002. International revenue represented 14% of our total revenue in fiscal year 2003 and 19% in fiscal year 2002.

LDX Analyzer unit sales decreased 5% worldwide in fiscal year 2003 compared to fiscal year 2002. 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%.

The GDx System, which we began selling in July 2002, generated revenue of \$2.4 million in fiscal year 2003. Approximately \$1.7 million of that amount related to single use cartridges, and \$700,000 related to GDx Analyzers.

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*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 year 2003 from \$17.0 million in fiscal year 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% in both fiscal years 2003 and 2002. Manufacturing spending increased 12%, in fiscal year 2003 compared to fiscal year 2002 which was consistent with the 12% increase in production of single-use test cassettes.

We have licensed certain technology used in some of our products. A 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 \$753,000 in fiscal year 2003 and \$755,000 in fiscal year 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 27% to \$11.7 million in fiscal year 2003 from \$9.2 million in fiscal year 2002. Sales and marketing expenses increased to 24% of sales in fiscal year 2003 from 22% in fiscal year 2002. Wages, benefits and other compensation costs increased \$1.1 million, or 29%, to \$5.0 million in fiscal year 2003. This increase was attributable to the hiring of 11 additional staff members. Product marketing costs, which include sample goods, distributor relations, product design and trade show expense, increased \$904,000 or 33%.

*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 24% to \$2.7 million in fiscal year 2003 from \$2.2 million in fiscal year 2002. Research and development expenses as a percentage of revenue increased to 6% in fiscal year 2003 from 5% in fiscal year 2002. This increase was attributable to the 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 expenses increased 9% to \$7.0 million in fiscal year 2003 from \$6.4 million in fiscal year 2002. The increase in such spending was attributable to \$591,000 of restructuring cost 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. As a percent of total revenue, general and administrative expenses decreased to 14% in fiscal year 2003 from 15% in fiscal year 2002.

*Litigation and Other Related.* Our legal and related expenses included professional consulting fees, court related costs and other fees relating to Roche litigation. Legal and related expenses increased 144% to \$307,000 in fiscal year 2003 from \$126,000 in fiscal year 2002. These costs related to professional legal services for several patent litigation issues with Roche which were resolved as part of

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the December 2003 agreement. These amounts were reclassified from general and administrative expenses in prior periods to disclose the full impact of this litigation had on our results of operations.

*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 year 2003 from \$449,000 in fiscal year 2002. This decrease was primarily the result of reduced yields on cash equivalents and marketable securities, together with higher bank service fees. Realized gains from sales of marketable securities were \$121,000 in fiscal year 2003 and \$11,000 in fiscal year 2002.

*Income Taxes.* We have historically experienced significant operating losses and operate in an industry subject to rapid technological changes. Therefore, at March 29, 2002, we provided a full valuation allowance on its deferred tax assets because of uncertainty regarding its ability to generate future taxable income and the realizability of the deferred tax assets. In 2003, we recorded a benefit of \$4.2 million from the partial reversal of our valuation allowance. Based on improved operating performance, we determined that a reduction of the valuation allowance was appropriate based on estimated taxable income through 2005 of approximately \$14.6 million. We recorded a \$266,000 tax provision for income taxes in fiscal year 2003 and a \$235,000 provision for income taxes in fiscal year 2002 which represented the estimated state income taxes payable, reduced for the use of NOLs and tax credit carryforwards.

*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. The loss from discontinued operations increased \$75,000 or 6% to \$1.4 million in fiscal year 2003 from \$1.3 million in fiscal year 2002. The primary reason for the increased loss was a smaller number of consumer testing events at which WellCheck provided its testing services, which reduced the amount of billing to sponsors.

We will recognize contingent sales proceeds pursuant to the terms of our sale of WellCheck, including the TEAMS royalty and performance remuneration, which will be recognized as earned as a component of discontinued operations.

*Loss on Sale of Discontinued Operations.* In fiscal year 2003, 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. We had no such charge in fiscal year 2002.



**Table of Contents****Liquidity and Capital Resources**

Cash flow information for the three years ended March 26, 2004 was as follows (in thousands):

	Mar 26, 2004	Mar 28, 2003	Mar 29, 2002
Cash, cash equivalents, marketable securities and long-term investments	\$ 23,602	\$ 26,081	\$ 22,107
Net cash provided by (used in) operating activities	(1,124)	3,713	6,004
Net cash used in investing activities	(7,165)	(6,880)	(7,476)
Net cash provided by financing activities	2,044	3,114	6,220
Net increase (decrease) in cash and cash equivalents	\$ (6,245)	\$ (53)	\$ 4,748

We have financed our operations primarily through the sale of equity securities, including employee stock option exercises, and net cash provided by operations. From our inception to March 26, 2004, we have raised \$84.3 million in net proceeds from equity financings. In addition to these amounts, we have available a \$4.0 million revolving bank line of credit agreement which was renewed in July 2003 and will expire in September 2004. 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 September 1, 2004. We did not borrow under this line of credit during fiscal year 2004. As a result, there were no limitations on our deposited assets.

*Cash Provided by (Used in) Operating Activities.* The use of \$1.1 million of cash for operations during fiscal year 2004 was primarily attributable to increased working capital other than cash. Reductions in accounts payable and accrued payroll, and the increase in accounts receivable combined for a net \$2.4 million use of cash. The reduction in trade payables related to the timing of inventory purchases and the decline in accrued payroll associated to reduced estimates for bonus and commissions. The increase in accounts receivable related to higher sales late in the quarter over the prior year. During the next 12 months the balance of these accounts should remain approximately the same or increase slightly. This was offset by net profit, which after non-cash adjustments for depreciation, tax benefits, and inventory reserves generated \$704,000 of cash flow. Additionally \$274,000 of cash was provided by reductions to prepaid expenses and other assets. This was attributed to the rescheduling of insurance policy renewals to into fiscal year 2005.

During fiscal year 2003 \$3.7 million of cash was provided by operating activities. Net profit less non-cash adjustments for depreciation, tax benefits, and the loss on the sale of WellCheck in total provided \$7.8 million, which was offset by a \$4.3 million use of cash for increases in inventories, account receivables and prepaid expenses. Additionally, \$227,000 was also consumed by decreased accrued payroll and related benefits.

*Cash Used in Investing Activities.* Spending on enhancements to manufacturing equipment, software, computers and leasehold improvements accounted for \$3.5 million of capital improvements during fiscal year 2004. Additionally, we made a \$3.7 million net purchase of marketable securities during the year. During fiscal year 2003 we made a net purchase of \$4.0 million of marketable securities and purchased \$2.9 million of plant, property and equipment. During fiscal year 2005, we intend to

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invest approximately \$4.0 million in capital purchases related to expansion of our manufacturing capacity, research and development, computer systems and tenant improvements.

*Cash Provided by Financing Activities.* Cash provided by financing activities for both fiscal year 2004 and 2003 relate to the issuance of common stock pursuant to the employee stock incentive and employee stock purchase plans. During fiscal year 2004 we raised \$2.0 million and in fiscal year 2003 we raised \$3.2 million from the two programs. The amount raised in the future will depend on the market value of our common stock, the prices of the incentive options and the purchase price relating to the employee stock purchase plan.

*Contractual Obligations*

The following summarizes our contractual obligations as of March 26, 2004, and the effect such obligations are expected to have on our liquidity and cash flow in future periods (in thousands):

Payments Due by Period	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years	No Specific Date	Total
Operating lease obligations(1)	\$ 1,032	\$ 2,189	\$	\$	\$	\$ 3,221
Purchase obligations	939	251	60			1,250
Other obligations(2)					1,427	1,427
	—	—	—	—	—	—
Total	\$ 1,971	\$ 2,540	\$ 60	\$	\$ 1,427	\$ 5,998

(1) This represents the minimum payments due under lease obligations.

(2) This represents the amount payable to certain of our officers if terminated for other than for cause. The amount is not identified with a specific date due to the fact the amounts are only payable at termination.

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 core operations for at least the next 12 months. Excluding the Roche settlement in fiscal year 2004, we have achieved positive net cash provided from operations for fiscal years 2000 through 2004 and we expect to continue to generate cash from operations for the foreseeable future.

In our efforts to grow, we are seeking to acquire technologies which could complement our current product offering. At this point, we have not found or targeted such technologies for purchase. However, should we acquire such technologies, in connection with such acquisitions we may need to use a significant amount of cash which could cause us to need to raise funds from debt or equity offerings. In the event that we would need additional financing for the operation of our business, we can draw upon our existing \$4.0 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 financing or credit facilities, or if these funds are available, they may not be available on satisfactory terms.

*Off-Balance Sheet Arrangements*

We do not have any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that are material to investors.

**Table of Contents****Quarterly Financial Data**

Quarter Ended	Mar. 26, 2004	Dec. 26, 2003	Sept. 26, 2003	June 27, 2003	Mar. 28, 2003	Dec. 27, 2002	Sept. 27, 2002	June 28, 2002
<i>(In thousands, except share data)</i>								
<b>(unaudited)</b>								
Revenue	\$ 11,942	\$ 13,363	\$ 13,357	\$ 13,714	\$ 13,480	\$ 12,022	\$ 11,906	\$ 11,132
Gross profit	6,090	7,197	7,740	8,169	7,903	6,453	6,661	7,099
Income (loss) from continuing operations	10,439	(3,951)	916	1,269	6,235	790	1,720	1,971
Gain (loss) from discontinued operations	5	5	9	15	(190)	(4,479)	(596)	(558)
Net income (loss)	\$ 10,444	\$ (3,946)	\$ 925	\$ 1,284	\$ 6,045	\$ (3,689)	\$ 1,124	\$ 1,413
Income from continuing operations per share								
Basic	\$ 0.74	\$ (0.28)	\$ 0.07	\$ 0.09	\$ 0.46	\$ 0.06	\$ 0.13	\$ 0.15
Diluted	\$ 0.73	\$ (0.28)	\$ 0.06	\$ 0.09	\$ 0.45	\$ 0.06	\$ 0.12	\$ 0.14
Loss from discontinued operations per share								
Basic	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00	\$ (0.02)	\$ (0.33)	\$ (0.05)	\$ (0.04)
Diluted	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00	\$ (0.01)	\$ (0.33)	\$ (0.04)	\$ (0.04)
Earnings (loss) per share:								
Basic	\$ 0.74	\$ (0.28)	\$ 0.07	\$ 0.09	\$ 0.44	\$ (0.27)	\$ 0.08	\$ 0.11
Diluted	\$ 0.73	\$ (0.28)	\$ 0.06	\$ 0.09	\$ 0.44	\$ (0.27)	\$ 0.08	\$ 0.10

**Critical Accounting Policies**

Our discussion and analysis of our financial condition and results of operations is 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 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.

*Revenue Recognition*

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 recorded as a reduction of revenue and 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

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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.

*Allowance for Bad Debts*

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. In the past, reserves, adjustments to reserve estimates and write-offs have not been significant.

*Inventory Valuation*

We state inventories at the lower of cost or market, cost being determined using standard costs which approximates the first-in, first-out (FIFO) method. We establish provisions for excess, obsolete and unusable inventories after evaluation of historical sales, forecasted sales, product expiration and current inventory levels. We charge to cost of revenue the increase to the provision for excess, obsolete and unusable inventory, the charge was \$651,000, \$92,000 and \$30,000 in fiscal year 2004, fiscal year 2003 and fiscal year 2002, respectively. 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.

*Income Taxes*

We use 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. We continually review our deferred tax asset to determine if a valuation allowance is required, primarily based on estimates of future taxable income. Changes in our assessment of the need for a valuation allowance could give rise to a valuation allowance and an expense in the period of the change.

*Stock Based Compensation*

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. The fair market value used to determine the amount of compensation is based on several estimates including expected stock volatility, expected life of grant, expected employee turnover.

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### **Recent Accounting Pronouncements**

In May 2003, FASB issued SFAS No. 150 ( SFAS 150 ), *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*. SFAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. This standard is effective for financial instruments entered into or modified after May 31, 2003. We adopted this standard and the adoption of this standard had no material impact on our financial statements.

In April 2003, the FASB issued SFAS No. 149 ( SFAS 119 ), *Amendment of Statement 133 of Derivative Instruments and Hedging Activities*. SFAS 149 amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts. This standard is effective for contracts entered into or modified after June 30, 2003. We adopted this standard and the adoption of this standard had 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 26, 2004, we had an accumulated deficit of \$27.2 million. Our first profitable quarter was the third quarter of fiscal year 1998, and our first profitable year was fiscal year 1998. We recorded a net profit of \$5.6 million for fiscal year 2002, a net profit of \$4.9 million for fiscal year 2003 and a net profit of \$8.7 million for fiscal year 2004. The following are some of 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;

manufacturing problems, efficiencies, capacity constraints or delays;

the timing of the introduction, availability and market acceptance of new tests and products;

changes in demand for our products based on changes in third-party reimbursement policies, changes in government regulation and other factors;

product pricing and discounts;

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

the timing, establishment and maintenance of strategic distribution arrangements and the success of the activities conducted under such arrangements;

the timing of significant orders from, and shipments to, customers;

competition from diagnostic companies with greater financial capital and resources;

costs and timing associated with business development activities, including potential licensing of technologies or intellectual property rights;

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additions or departures of our key personnel;

promotional program spending by both domestic and European pharmaceutical companies;

variations in the mix of products sold; and

litigation or the threat of litigation.

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

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

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

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

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

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

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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 example, in fiscal year 2004, we entered into a settlement agreement and license agreement with Roche, which settled all existing patent litigation between the parties on a worldwide basis. The settlement included a lump sum payment by us to Roche in the amount of \$7.0 million and the dismissal of all patent claims between the parties. As a part of the settlement, we will pay Roche an ongoing royalty and Roche will grant an irrevocable, non-exclusive, worldwide license to us for its patents related to HDL cholesterol. In addition, the parties have also agreed upon a mechanism for the resolution of future patent infringement disputes. We believe that any such dispute resolution will confirm that our HDL cholesterol test cassette, currently under development, does not infringe Roche's patents. If however, upon the resolution of any such dispute, it is ultimately determined that our new HDL cholesterol test cassette is covered by Roche's patents, we will pay Roche the same ongoing royalty.

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 trade secrets, or be capable of protecting our rights to our trade secrets.

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

Our current products incorporate technologies that are the subject of patents issued to, and patent applications filed by, others. We have obtained licenses for certain of these technologies. We may in the future be required to negotiate to obtain licenses for new products. Some of our current licenses are subject to rights of termination and may be terminated. Our licensors may not abide by their contractual obligations and, as a result, may limit the benefits we currently derive from their licenses. We may be unable to renegotiate or 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, maintain or enforce necessary licenses on commercially reasonable terms or to identify and implement alternative approaches could prevent us from introducing our products and severely harm our business.

***Our stock price has been highly volatile and 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. For example, between March 28, 2003 and March 26, 2004, the price of our common stock, as reported on the NASDAQ National Market System, has ranged from a low of \$6.20 to a high of

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\$12.89. 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;

litigation or threat of litigation;

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;

our failure to achieve, or changes in, financial estimates by securities analysts and comments or opinions about us by securities analysts or major shareholders;

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 to other forms of investment information, including newsletters and research publications, could result in a significant 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.

***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 their patients' healthcare insurers, 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,



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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 both existing and new medical products and services;

healthcare providers are moving toward a system in which employers are requiring participants to bear a greater burden of the cost of their healthcare benefits which could result in 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 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.

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

To increase revenue and achieve sustained profitability, we will have to successfully maintain our existing distribution relationships and develop new distribution relationships. We depend 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 or utilize the leverage of broader product lines sold through the distributor, those distributors may de-emphasize or decline to carry our products. In addition, our distributors' order decision-making process is complex and involves several factors, including end-user demand, warehouse allocation and marketing resources, which can make it difficult to accurately predict total sales for the quarter until late in the quarter. In order to keep our products included in distributors' marketing programs, in the past we have provided promotional goods or made short-term pricing concessions. The discontinuation of promotional goods or pricing concessions could have a negative effect on our business. Our distributors could also modify their business practices, such as payment terms, inventory levels or order patterns.

For example, as part of our practice of providing periodic promotional incentives to our distribution partners, we have historically offered small discounts from standard distributor pricing to such partners in connection with large unit volume purchases. Throughout the course of fiscal year 2004, we experienced increasing demand by our distribution partners to purchase at such discounts toward the end of each quarter. We became increasingly concerned about the future impact on end-user pricing and the inefficiencies in our operations that result from month to month swings in shipping volume. As a result, beginning in the fourth quarter of fiscal year 2004, we decided to reduce the amount of product we sold to our distribution partners at a discount to their standard price, which had an adverse impact on our operating results. If we are unable to maintain successful relationships with distributors or expand our distribution channels or we experience unexpected changes in payment terms, inventory levels or other practices by our distributors, our business will suffer.

***We may be unable to accurately predict future sales through our distributors, which could harm our ability to efficiently manage our internal resources to match market demand***

Our product sales are primarily made through our network of over 85 domestic and international distributors. As a result, our financial results, quarterly product sales, trends and comparisons are affected by fluctuations in the buying patterns of end-user customers and our distributors, and by the changes in inventory levels of our products held by these distributors. We have only limited visibility over the inventory levels of our products held by our domestic and international distributors. While we attempt to assist our distributors in maintaining targeted stocking level of our products, we may not consistently be accurate or successful. This process involves the exercise of judgment and use of assumptions as to future uncertainties including end-user customer demand, and the reaction of our distributors to our new quarterly pricing policy. Consequently, actual results could differ from our estimates. Inventory levels of our products held by our distributors may exceed or fall below the levels we consider desirable on a going-forward basis, which may harm our financial results due to unexpected

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buying patterns of our distributors or our ability to efficiently manage or invest in internal resources, such as manufacturing and shipping capacity, to meet the actual demand for our products.

***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 business is based on the sale of diagnostic products that physicians and other healthcare providers can administer in their own facilities without sending samples to laboratories. Thus, our competition consists primarily of clinical reference laboratories and hospital-based laboratories that use automated testing systems, as well as manufacturers of other rapid diagnostic tests. 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 cost effective and time saving alternatives to other rapid diagnostic tests as well as to clinical and hospital laboratories. Even if we can demonstrate that our products are more cost effective and save time, physicians and other healthcare providers may resist changing their established source of such tests. 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 product lines than us, have greater name recognition than us and offer discounts as a competitive tactic. In addition, several smaller companies, including Polymer Technology Systems, Inc. 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;

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

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

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

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 the LDX System currently contributes the vast majority of our revenue, and we expect the GDX System to contribute a 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 we do not develop market and introduce new tests and products to 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;

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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. In addition, our business strategy includes entering into agreements with clinical and commercial collaborators and other third parties for the development, clinical evaluation and marketing of existing products and products under development. These agreements may be subject to rights of termination and may be terminated without our consent. The parties to these agreements also may not abide by their contractual obligations to us and may discontinue or sell their current lines of business. Research performed under a collaboration for which we receive or provide funding may not lead to the development of products in the timeframe expected, or at all. If these agreements are terminated earlier than expected, or if third parties do not perform their obligations to us properly and on a timely basis, we may not be able to successfully develop new products as planned, or at all.

***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. Significant additional resources, implementation of additional manufacturing equipment or changes in our manufacturing processes have been, and may continue to be, required for the scaling-up of each new product prior to commercialization or in order to meet increasing customer demand once commercialization begins, and this work may not be completed successfully or efficiently. 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 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;

human error;

manufacturing process variances and impurities; and

decreased manufacturing equipment performance.

Our LDX manufacturing equipment 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 could be required to use our machinery more hours per day and the down time resulting from equipment failure could increase;

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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 of our 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

our new manufacturing line is operating at 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 manufacture the majority of our dry chemistry cassettes on a single production line. A second manufacturing line is currently used for overflow production and 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 year 2004 and 14% in fiscal year 2003. 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;

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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.

***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 year 2004. In fiscal year 2004, Physicians Sales and Service (PSS) accounted for approximately 23% of our total revenue, Henry Schein Inc. (Henry Schein) accounted for approximately 9% and McKesson Medical Surgical (McKesson) accounted for 8% of our total revenue. In fiscal year 2003, PSS accounted for approximately 22% of our total revenue, McKesson accounting for 9% of our total revenue, and Henry Schein accounted for approximately 7% of our total revenue. We have experienced periods in which sales to some of our major customers, as a percentage of total revenue, have fluctuated due to delays or failures to place expected orders. 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.

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***Recently enacted and proposed changes in securities laws and regulations will increase our costs***

The Sarbanes-Oxley Act of 2002 along with other recent and proposed rules from the Securities and Exchange Commission and NASDAQ require changes in our corporate governance, public disclosure and compliance practices. Many of these new requirements will increase our legal and financial compliance costs, and make some corporate actions more difficult, such as proposing new or amendments to stock option plans, which now require shareholder approval. These developments could make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These developments also could make it more difficult for us to attract and retain qualified executive officers and qualified members of our board of directors, particularly to serve on our audit committee.

***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 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.



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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 from sales of such products, which would severely harm our business.

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

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

***Although in recent times there have been signs of a general economic upturn in the United States, it is uncertain as to how strongly this upturn may impact our markets over the next year***

The primary customers for our products are physician office laboratories and entities conducting health promotion programs. Beginning in 2001, a general economic downturn in the United States reduced demand for our products and our customers' capital spending in most of the markets that we serve. This general economic downturn continued through 2003 but has stabilized throughout 2004. However, it is uncertain as to how strongly this general economic upturn may impact the markets we

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serve over the next year and whether the upturn can be sustained. Overall, our customers' spending decisions are still being closely scrutinized. Any future 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 again likely result in a decline in demand for our products and could adversely affect our business.

***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 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.

***Our business could be negatively affected by the loss of key personnel or our inability to hire qualified personnel***

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.

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***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 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 harm 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.

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*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 anti-takeover plan. The issuance of preferred stock under certain circumstances could have the effect of delaying or preventing an acquisition of our company or otherwise adversely affecting the rights of the holders of our stock. The poison pill may have the effect of rendering more difficult or discouraging an acquisition of our company which is deemed undesirable by our board of directors. The poison pill may cause substantial dilution to a person or group attempting to acquire us on terms or in a manner not approved by our board of directors, except pursuant to an offer conditioned on the negation, purchase or redemption of the rights issued under the poison pill.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

**Quantitative Disclosures**

Our exposure to market risks is inherent in our operations, primarily to interest rates relating to our investment portfolio.

We 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.

Generally we hold our marketable securities until maturity. These securities have maturity dates that do not exceed fiscal year 2008 and have predominately fixed interest rates. We have concluded that the income on our investments would not be significantly impacted by short term changes in interest rates. When the securities mature and the principal is reinvested, the yield will reflect the market conditions at that time. Fluctuations in short-term interest rates may change the fair market value of our investments; however, as the marketable securities approach maturity, the fair value will approximate our cost basis.

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. As of March 26, 2004, we had outstanding forward contracts to purchase £375,000 for approximately \$607,000. The open contracts mature at various dates through July 15, 2004 and hedge certain forecasted inventory purchases denominated in the British Pound Sterling. The unrealized gain on the forward contracts as of March 26, 2004 was \$88,000, 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.

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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 (in thousands)	2005	2006	2007	2008	Total	Fair Value	
Cash, cash equivalents	\$ 2,502	\$	\$	\$	\$ 2,502	\$ 2,502	
Short-term marketable securities	\$ 11,300	\$	\$	\$	\$ 11,300	\$ 11,300	
Weighted average interest rate	3.73%						
Long-term marketable securities	\$	\$ 8,976	\$ 307	\$ 517	\$ 9,800	\$ 9,800	
Weighted average interest rate	2.99%					3.22%	4.26%

**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.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

Our consolidated financial statements and the independent registered public accounting firm report appear on pages F-1 to F-27 of this Annual Report. See Item 15 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.

**ITEM 9A. CONTROLS AND PROCEDURES**

*Evaluation of disclosure controls and procedures.* Our management evaluated, with the participation of our Chief Executive Officer and our Chief Financial Officer, the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act of 1934, as amended) as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that information we are required to disclose in reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

*Changes in internal control over financial reporting.* There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the period

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covered by this Annual Report on Form 10-K that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**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 **Proposal One Election of Directors** and **Section 16(a) Beneficial Ownership Reporting Compliance** contained in our Proxy Statement related to the 2004 Annual Meeting of Shareholders to be held August 18, 2004, 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 our 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 our 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 our 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 our Proxy Statement.

**ITEM 14. 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 Registered Public Accounting Firm** in our Proxy Statement.

**Table of Contents****PART IV**

## ITEM 15. 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:

	<u>Page</u>
Report of Independent Registered Public Accounting Firm	F-1
Consolidated Balance Sheets at March 26, 2004 and March 28, 2003	F-2
Consolidated Statements of Operations for the years ended March 26, 2004, March 28, 2003 and March 27, 2002	F-3
Consolidated Statement of Changes in Shareholders' Equity for the years ended March 26, 2004, March 28, 2003 and March 29, 2002	F-4
Consolidated Statements of Cash Flows for the years ended March 26, 2004, March 28, 2003 and March 29, 2002	F-5
Notes to Consolidated Financial Statements	F-6
(a)(2) <i>Financial Statement Schedules.</i>	
Schedule II Valuation and Qualifying Accounts	F-26

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
10.17.9(6)	Revolving Line of Credit Note effective July 1, 2003 by and between Wells Fargo Bank and Registrant
10.20(7)	1997 Stock Incentive Program, as amended, and form of agreement thereto
10.21(8)	1999 Nonstatutory Stock Option Plan, as amended, and form of agreement thereto
10.25(9)	Employment Agreement between Registrant and Thomas E. Worthy dated August 6, 1999
10.26(9)	Employment Agreement between Registrant and Terry L. Wassmann dated March 28, 2000
10.29(10)	2000 Stock Incentive Program, as amended, and form of agreement thereto

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10.32(11)	Employment Agreement between Registrant and William W. Burke dated March 14, 2001
10.37(12)	Lease Agreement between Registrant and the BIV Group dated July 23, 2001
10.38(13)	2002 Employee Stock Purchase Plan and form of agreement thereto
10.39(14)	Stock Purchase Agreement dated December 23, 2002 between Registrant, WellCheck Inc. and ImpactHealth.com, Inc.
10.40(15)	Amended and Restated Severance Arrangement between Registrant and Warren E. Pinckert II dated June 14, 2001
10.40.1(15)	First Amendment to Amended and Restated Severance Arrangement between Registrant and Warren E. Pinckert II dated March 27, 2003
10.41(15)	Change of Control Severance Agreement between Registrant and Warren E. Pinckert II dated June 14, 2001
10.41.1(15)	First Amendment to Change of Control Severance Agreement between Registrant and Warren E. Pinckert II dated January 23, 2003
10.41.2	Amended and Restated Change of Control Severance Agreement between Registrant and Warren E. Pinckert II dated March 25, 2004
10.42(15)	Severance Agreement between Registrant and William W. Burke dated July 17, 2001
10.43(15)	Change of Control Severance Agreement between Registrant and William W. Burke dated July 21, 2001
10.43.1(15)	First Amendment to Change of Control Severance Agreement between Registrant and William W. Burke dated January 23, 2003
10.43.2	Amended and Restated Change of Control Severance Agreement between Registrant and William W. Burke dated March 25, 2004
10.46(15)	Severance Agreement between Registrant and Terry L. Wassmann dated July 17, 2001
10.46.1(15)	First Amendment to Severance Agreement between Registrant and Terry L. Wassmann dated January 23, 2003
10.47(15)	Change of Control Severance Agreement between Registrant and Terry L. Wassmann dated January 23, 2003
10.47.1(15)	First Amendment to Change of Control Severance Agreement between Registrant and Terry L. Wassmann dated January 23, 2003
10.47.2	Amended and Restated Change of Control Severance Agreement between Registrant and Terry L. Wassmann dated March 25, 2004
10.48(15)	Severance Agreement between Registrant and Thomas E. Worthy dated July 19, 2001
10.48.1(16)	First Amendment to Severance Agreement between Registrant and Thomas E. Worthy dated October 10, 2003
10.50(15)	Employment Agreement between Registrant and Donald P. Wood dated March 31, 2003
10.51(15)	Severance Agreement between Registrant and Donald P. Wood dated April 1, 2003
10.51.1(16)	First Amendment to Severance Agreement between Registrant and Donald P. Wood dated October 10, 2003
10.52(16)	Change of Control Severance Agreement between Registrant and Donald P. Wood dated October 10, 2003
10.52.1	Amended and Restated Change of Control Severance Agreement between Registrant and Donald P. Wood dated March 25, 2004



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10.54(16)	Change of Control Severance Agreement between Registrant and Thomas E. Worthy dated October 10, 2003
10.54.1	Amended and Restated Change of Control Severance Agreement between Registrant and Thomas E. Worthy dated March 25, 2004
10.55	Change of Control Severance Agreement between Registrant and Kenneth F. Miller dated June 2, 2004
23.1	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (see page 65)
31.1	Certification of Chief Executive Officer under Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended
31.2	Certification of Chief Financial Officer under Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended
32	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. 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.

(6) Incorporated by reference to exhibit filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended June 27, 2003.

(7) 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.

(8) 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.

(9) Incorporated by reference to exhibits filed with Registrant's Annual Report on Form 10-K for the fiscal year ended March 31, 2000.

(10) Incorporated by reference to exhibit filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended September 26, 2003.

(11) Incorporated by reference to exhibits filed with Registrant's Annual Report on Form 10-K for the fiscal year ended March 30, 2001.

(12) Incorporated by reference to exhibits filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended September 28, 2001.

(13) 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.

(14) 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.

(15) Incorporated by reference to exhibits filed with Registrant's Annual Report on Form 10-K for the fiscal year ended March 28, 2003.

(16) Incorporated by reference to exhibit filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended December 26, 2003.

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

On January 21, 2004, we furnished a current report on Form 8-K reporting under Item 12 of Form 8-K that on January 21, 2004 we were issuing a press release and holding a conference call regarding our financial results for the fiscal quarter ended December 26, 2003.

(c) *Exhibits.*

See Item 15(a)(3) above.

(d) *Financial Statement Schedules.*

See Item 15(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

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

Date: June 8, 2004

**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 (Principal Executive Officer)	June 8, 2004
/s/ WILLIAM W. BURKE <hr/> (William W. Burke)	Vice President of Finance, Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)	June 8, 2004
/s/ JOHN H. LANDON <hr/> (John H. Landon)	Director	June 8, 2004
/s/ MICHAEL D. CASEY <hr/> (Michael D. Casey)	Director	June 8, 2004

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Signature	Title	Date
/s/ JOHN L. CASTELLO <hr/>	Director	June 8, 2004
(John L. Castello)		
/s/ ELIZABETH H. DÁVILA <hr/>	Director	June 8, 2004
(Elizabeth H. Dávila)		
/s/ STUART HEAP <hr/>	Director	June 8, 2004
(Stuart Heap)		
/s/ LARRY Y. WILSON <hr/>	Director	June 8, 2004
(Larry Y. Wilson)		

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and

Shareholders of Cholestech Corporation

In our opinion, the financial statements listed in the index appearing under Item 15(a)(1) present fairly, in all material respects, the financial position of Cholestech Corporation at March 26, 2004 and March 28, 2003, and the results of their operations and their cash flows for each of the three years in the period ended March 26, 2004 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 15(a)(2) presents fairly, in all material respects, the information set forth therein when read in conjunction with the related 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 the standards of the Public Company Accounting Oversight Board (United States), 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  
June 8, 2004

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**CHOLESTECH CORPORATION**  
**CONSOLIDATED BALANCE SHEETS**

	<b>March 26, 2004</b>	<b>March 28, 2003</b>
<i>(in thousands, except share data)</i>		
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 2,502	\$ 8,747
Marketable securities	11,300	4,776
Accounts receivable, net	6,038	5,195
Inventories, net	6,083	6,806
Prepaid expenses and other assets	1,715	1,989
Note receivable	200	250
Deferred tax assets	2,100	2,100
	29,938	29,863
Property and equipment, net	8,257	7,491
Long-term investments	9,800	12,558
Long term deferred tax assets	15,235	2,100
	63,230	52,012
	\$ 63,230	\$ 52,012
<b>Liabilities and Shareholders' Equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 3,149	\$ 3,971
Accrued payroll and benefits	2,489	3,173
Other liabilities	314	140
	5,952	7,284
	5,952	7,284
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; 14,095,075 and 13,698,533 shares issued and outstanding at March 26, 2004 and March 28, 2003, respectively	84,286	82,242
Accumulated other comprehensive income	149	73
Accumulated deficit	(27,157)	(37,587)
	57,278	44,728
	57,278	44,728
Total liabilities and shareholders' equity	\$ 63,230	\$ 52,012
	\$ 63,230	\$ 52,012

See accompanying notes to consolidated financial statements.

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

Fiscal Year Ended	March 26, 2004	March 28, 2003	March 29, 2002
<i>(in thousands, except per share data)</i>			
Revenue	\$ 52,376	\$48,541	\$41,747
Cost of revenue	23,180	20,424	17,040
Gross profit	29,196	28,117	24,707
Operating expenses:			
Sales and marketing	12,654	11,737	9,241
Research and development	3,159	2,722	2,201
General and administrative	8,153	7,008	6,447
Other operating costs	250		
Litigation and other related	7,786	307	126
Total operating expenses	32,002	21,774	18,015
Income (loss) from operations	(2,806)	6,343	6,692
Interest and other income, net	278	438	449
Income (loss) before taxes	(2,528)	6,781	7,141
Provision (benefit) for income taxes			
Current	225	266	289
Deferred	(11,426)	(4,200)	
Total provision (benefit) for income taxes	(11,201)	(3,934)	289
Income from continuing operations	8,673	10,715	6,852
Loss from sale of discontinued operations		(4,445)	
Gain (loss) from discontinued operations	34	(1,377)	(1,302)
Net income	\$ 8,707	\$ 4,893	\$ 5,550
Income from continuing operations per share:			
Basic	\$ 0.62	\$ 0.79	\$ 0.54
Diluted	\$ 0.61	\$ 0.76	\$ 0.50
Gain (loss) from discontinued operations per share:			
Basic	\$ 0.01	\$ (0.43)	\$ (0.10)
Diluted	\$ 0.00	\$ (0.41)	\$ (0.10)
Net income per share:			
Basic	\$ 0.63	\$ 0.36	\$ 0.44
Diluted	\$ 0.61	\$ 0.35	\$ 0.40
Shares used to compute net income (loss) per share:			

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Basic	13,922	13,551	12,658
Diluted	14,235	14,077	13,730

See accompanying notes to consolidated financial statements.

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**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 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 authorized but unissued stock	(13,425)	(176)			(176)
Balance at March 28, 2003	13,698,553	82,242	73	(37,587)	44,728
Net income				8,707	8,707
Change in unrealized gain on available-for-sale securities			(66)		(66)
Change in future currency contracts			142		142
Comprehensive income					8,783
Issuance of Common Stock pursuant to employee stock purchase plan and exercise of stock options	396,522	2,044			2,044
Tax benefit on non-qualified stock options				1,723	1,723
Balance at March 26, 2004	14,095,075	\$84,286	\$149	\$(27,157)	\$57,278

See accompanying notes to consolidated financial statements.



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

Fiscal Year Ended	March 26, 2004	March 28, 2003	March 29, 2002
<i>(in thousands)</i>			
<b>Cash Flows From Operating Activities:</b>			
Net income	\$ 8,707	\$ 4,893	\$ 5,550
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	2,709	2,553	2,608
Change in allowance for doubtful accounts	54	59	163
Change in inventory reserve	651	92	30
Change in allowance for sales returns	(5)	(20)	(58)
Deferred tax assets	(11,426)	(4,200)	
Loss on sale of WellCheck		4,445	
Stock acceleration charge		(72)	161
Changes in assets and liabilities:			
Accounts receivable	(892)	(1,509)	(816)
Inventories	72	(1,941)	(1,345)
Prepaid expenses and other assets	274	(845)	(435)
Notes receivable	50		
Accounts payable and accrued liabilities	(808)	461	(1,079)
Accrued payroll and benefits	(684)	(227)	1,200
Other liabilities	174	24	25
	<u>          </u>	<u>          </u>	<u>          </u>
Net cash provided by (used in) operating activities	(1,124)	3,713	6,004
	<u>          </u>	<u>          </u>	<u>          </u>
<b>Cash Flows From Investing Activities:</b>			
Purchases of marketable securities	(47,894)	(49,427)	(36,867)
Maturities of marketable securities	44,204	45,472	31,805
Purchase of property and equipment	(3,475)	(2,925)	(2,414)
	<u>          </u>	<u>          </u>	<u>          </u>
Net cash used in investing activities	(7,165)	(6,880)	(7,476)
	<u>          </u>	<u>          </u>	<u>          </u>
<b>Cash Flows From Financing Activities:</b>			
Issuance of common stock	2,044	3,218	6,220
Purchase of authorized but unissued stock		(104)	
	<u>          </u>	<u>          </u>	<u>          </u>
Net cash provided by financing activities	2,044	3,114	6,220
	<u>          </u>	<u>          </u>	<u>          </u>
Net increase (decrease) in cash and cash equivalents	(6,245)	(53)	4,748
Cash and cash equivalents at beginning of year	8,747	8,800	4,052
	<u>          </u>	<u>          </u>	<u>          </u>
Cash and cash equivalents at end of year	\$ 2,502	\$ 8,747	\$ 8,800
	<u>          </u>	<u>          </u>	<u>          </u>
<b>Supplemental disclosures of cash flow information:</b>			
Cash paid for income taxes	\$ 590	\$ 59	\$ 160
Cash paid for legal settlement	\$ 7,000		\$ 855
Tax benefits of nonqualified stock options	\$ 1,723		

See accompanying notes to consolidated financial statements.



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**CHOLESTECH CORPORATION**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Summary of Significant Accounting Policies**

*Description of the Company*

Cholestech Corporation (the Company), incorporated under the laws of the State of California, is a leading provider of diagnostic tools and information for immediate risk assessment and therapeutic monitoring of heart disease and diabetes. The Company currently manufactures the LDX System, which includes the LDX Analyzer and a variety of single-use test cassettes, and markets 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. The Company's 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.

The Company also markets and distributes the GDX System under a multi-year global distribution agreement with Provalis Diagnostics Ltd. The Cholestech GDX is a hemoglobin A1c (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.

*Fiscal year end*

The Company's fiscal year is a 52 - 53 week period ending on the last Friday in March. Fiscal years 2004, 2003 and 2002 were comprised of 52 weeks.

*Principles of consolidation*

The consolidated financial statements include the accounts of the Company and the accounts of WellCheck, Inc. (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 its customers, the price is fixed and determinable and collection is reasonably assured. Provisions for discounts to customers, returns or other adjustments are recorded as a reduction of revenue and provided for in the same period that the related product sales are recorded based upon analyses of historical discounts and returns. The Company recognizes revenue associated with services upon completion of the services to be performed under contract when all obligations are satisfied, and collection is reasonably assured. Its general terms of sale are FOB shipping point and revenue recognition at time of shipment. When the terms of sale are FOB receiving point,

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revenue is recognized when the products have reached the destination point and collections are 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, known improvements in design or changes in reliability.

The Company maintains a product return allowance, when required, 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.

The Company will from time to time provide free goods to customers as samples for the purpose of motivating end users who may be potential long-term users of the Company's products. In addition, on occasion the Company provides free goods to customers as part of a sale transaction as an incentive. The cost of free goods associated with revenue transactions is charged to cost of goods sold.

*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 26, 2004 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 \$30,000 in unrealized gains as of March 26, 2004 included in accumulated other comprehensive income in shareholders' equity and \$96,000 in unrealized gains as of March 28, 2003.

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The cost and fair market value of available-for-sale securities as of March 26, 2004 are as follows (in thousands):

	Cost	Unrealized Gain (Loss)	Fair Market Value	Maturity date
<b>Short-term marketable securities</b>				
Commercial paper	\$ 283	\$	\$ 283	September 2004 January 2005
Corporate bonds	6,565	(3)	6,562	May 2004 March 2005
Government agency	4,444	11	4,455	May 2004 February 2005
	<u>\$ 11,292</u>	<u>\$ 8</u>	<u>\$ 11,300</u>	
<b>Long-term marketable securities</b>				
Commercial paper	\$ 516	\$ 1	\$ 517	May 2007
Corporate bonds	3,785	11	3,796	May 2005 January 2006
Government agency	5,477	10	5,487	April 2005 January 2005
	<u>\$ 9,778</u>	<u>\$ 22</u>	<u>\$ 9,800</u>	

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

	Cost	Unrealized Gain	Fair Market Value	Maturity date
<b>Short-term marketable securities</b>				
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
<b>Long-term marketable securities</b>				
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>	

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***Derivative Instruments***

All derivatives are recognized as either assets or liabilities on the balance sheet and are carried 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 shareholders' 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.

As of March 26, 2004, the Company had outstanding forward contracts to purchase £375,000 for approximately \$607,000. The open contracts mature at various dates through July 15, 2004 and hedge certain forecasted inventory purchases denominated in the British Pound Sterling. The unrealized gain on the forward contracts as of March 26, 2004 was \$88,000, 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 historically such amounts, in the aggregate, have been immaterial. Provisions are made for estimated product returns, which historically have been immaterial.



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Significant revenue concentration (in thousands):

	March 26, 2004		March 28, 2003	
	Revenue	Percent of Total	Revenue	Percent of Total
Customer A	\$ 11,967	23%	\$ 10,909	22%
Customer B			4,461	9
Total	\$ 11,967	23%	\$ 15,370	31%

Significant accounts receivable concentrations (in thousands):

	March 26, 2004		March 28, 2003	
	Receivable Balance	Percent of Total	Receivable Balance	Percent of Total
Customer A	\$ 994	16%	\$ 848	16%
Customer B	851	14	626	12
Customer C	812	13		
Total	\$ 2,657	43%	\$ 1,474	28%

*Inventories*

Inventories are stated at the lower of cost or market, cost being determined using standard costs which approximates the first-in, first-out (FIFO) method. Cost includes direct materials, direct labor and manufacturing overhead. Reserves for potentially excess and obsolete inventory are made based on management analysis of inventory levels, planned changes in material usage and future sales forecasts.

*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. Estimated useful lives are 2 to 7 years for machinery and equipment, 3 years for computer equipment, 5 years for furniture and fixtures and 14 to 17 years for patents. 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.

**Table of Contents***Goodwill*

The Company reviewed its goodwill for impairment and determined that no impairment loss existed as of March 30, 2001 and March 29, 2002. All goodwill related to the Company's WellCheck subsidiary which was sold in December 2002. The goodwill was written off and included as part of the loss from the sale of discontinued operations on the consolidated statements of operations.

*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 repair costs of the LDX Analyzer and replacement costs of defective single-use test cassettes. The warranty period for the LDX Analyzer is one year and for single use test cassettes is the self-life of the product. The warranty cost of the GDx 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 and repair costs, known design changes, 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 fiscal year ended March 26, 2004 were as follows:

Fiscal Year Ended	March 26, 2004	March 28, 2003
Balance at the beginning of the year	\$ 116,000	\$ 116,000
Accruals and charges for warranty for the year	970,000	391,000
Cost of repairs and replacements	(772,000)	(391,000)
	<u>          </u>	<u>          </u>
Balance at the end of the year	\$ 314,000	\$ 116,000
	<u>          </u>	<u>          </u>

*Advertising costs*

The cost of advertising is expensed as incurred. Advertising expenses were \$281,000, \$175,000 and \$263,000 for fiscal 2004, 2003 and 2002, 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 2004 included a \$10.2 million gain from an income tax benefit which resulted from the reversal of the balance of the valuation allowance previously established for the Company's deferred tax assets. Net income in fiscal 2003 included a \$4.2 million gain from the reversal of a portion of the valuation allowance. Prior to fiscal 2003, the Company had experienced significant operating losses and operated in an industry subject to rapid technological change. Therefore, the Company believed that

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there was sufficient uncertainty regarding its 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 as of March 29, 2002. The Company continually reviews its deferred tax asset to determine if a valuation allowance is required, primarily based on its estimates of future taxable income. Changes in the Company's assessment of the need for a valuation allowance could give rise to a valuation allowance and an 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 reconciles the numerator (net income or loss) and denominator (number of shares) used in the basic and diluted per share computations.

	March 26, 2004	March 28, 2003	March 29, 2002
<i>(In thousands, except share data)</i>			
<b>Income</b>			
Income from continuing operations	\$ 8,673	\$ 10,715	\$ 6,852
Income (loss) from discontinued operations	34	(5,822)	(1,302)
	<u>          </u>	<u>          </u>	<u>          </u>
Net income	<u>\$ 8,707</u>	<u>\$ 4,893</u>	<u>\$ 5,550</u>
<b>Shares</b>			
Basic	13,922	13,551	12,658
Effect of dilutive securities	313	526	1,072
	<u>          </u>	<u>          </u>	<u>          </u>
Diluted	<u>14,235</u>	<u>14,077</u>	<u>13,730</u>
<b>Per share continuing operations:</b>			
Basic	\$ 0.62	\$ 0.79	0.54
Effect of dilutive securities	(0.01)	(0.03)	(0.04)
	<u>          </u>	<u>          </u>	<u>          </u>
Diluted	<u>\$ 0.61</u>	<u>\$ 0.76</u>	<u>\$ 0.50</u>
<b>Per share discontinued operations:</b>			
Basic	\$ 0.01	\$ (0.43)	\$ (0.10)
Effect of dilutive securities	(0.01)	(0.02)	
	<u>          </u>	<u>          </u>	<u>          </u>
Diluted	<u>\$ 0.00</u>	<u>\$ (0.41)</u>	<u>\$ (0.10)</u>
<b>Per share continuing operations:</b>			
Basic	\$ 0.63	\$ 0.36	\$ 0.44
Effect of dilutive securities	(0.02)	(0.01)	(0.04)
	<u>          </u>	<u>          </u>	<u>          </u>
Diluted	<u>\$ 0.61</u>	<u>\$ 0.35</u>	<u>\$ 0.40</u>

Options to purchase 1,410,172, 1,811,253 and 472,950 shares of common stock were considered anti-dilutive because the respective exercise prices were greater than the average fair market value of common stock as of March 26, 2004, March 28, 2003 and March 29, 2002, respectively.

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*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.

*Use of estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the 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. The primary estimates underlying the Company's financial statements include allowance for doubtful accounts receivable, reserves for obsolete, expiring and slow moving inventory, income taxes, accruals for payroll, product warranty and accruals for other liabilities. 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* ( SFAS 123 ) as amended by SFAS No. 148, *Accounting for Stock-Based Compensation - Transition and Disclosure* ( SFAS 148 ). As permitted under SFAS 148, the Company uses the intrinsic value-based method of Accounting Principles Board ( APB ) Opinion No. 25, *Accounting for Stock Issued to Employees* ( APB 25 ), to account for its employee stock-based compensation plans. Under APB 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 123 as amended by SFAS 148. Had the compensation cost for the Company's stock option and stock purchase plans been

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determined based on the fair market value of the options at the grant dates, as prescribed in SFAS 123, the Company's net income and net income per share would have been as follows:

Fiscal Year Ended	March 26, 2004	March 28, 2003	March 29, 2002
<i>(In thousands, except per share data)</i>			
Net income as reported	\$ 8,707	\$ 4,893	\$ 5,550
Deduct: total stock-based employee compensation expense determined under fair value based method for all awards, net of tax	(2,646)	(2,182)	(1,066)
Net income pro forma	<u>\$ 6,061</u>	<u>\$ 2,711</u>	<u>\$ 4,484</u>
Net income per share:			
As reported basic	\$ 0.63	\$ 0.36	\$ 0.44
Pro forma basic	\$ 0.44	\$ 0.20	\$ 0.35
As reported diluted	\$ 0.61	\$ 0.35	\$ 0.40
Pro forma diluted	\$ 0.43	\$ 0.19	\$ 0.32

The fair value is estimated using the Black-Scholes valuation model, with the following assumptions used during the applicable periods:

Fiscal Year Ended	March 26, 2004	March 28, 2003	March 29, 2002
Stock options:			
Expected volatility	85.0%	95.0%	81.0%
Risk free interest rate	1.0%	1.5%	2.5%
Dividend yield	0.0%	0.0%	0.0%
Fair value of stock options granted (per share)	\$ 6.53	\$ 8.33	\$ 9.34
Expected life	7 Years	7 Years	7 Years
Stock purchase rights:			
Expected volatility	85.0%	69.0%	81.0%
Dividend yield	0.0%	0.0%	0.0%
Fair value of stock purchase rights (per share)	\$ 1.36	\$ 1.72	\$ 1.21
Weighted average exercise price	\$ 5.38	\$ 6.46	\$ 6.13
Expected life	6 Months	6 Months	6 Months

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.

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The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS 123 and Emerging Issues Task Force No. 96-18, *Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods and Services* ( EITF 96-18 ), and FASB Interpretation No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plan* ( FIN 28 ). This provides guidance for accounting for stock options given to non-employees in exchange for goods and services.

The Company did not grant stock options or have outstanding options to non employees for fiscal year 2004, fiscal 2003 and fiscal 2002.

### *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 May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* ( SFAS 150 ). SFAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. This standard is effective for financial instruments entered into or modified after May 31, 2003. The Company adopted this standard and the adoption of this standard had no material impact on its financial statements.

In April 2003, the FASB issued SFAS No. 149, *Amendment of Statement 133 of Derivative Instruments and Hedging Activities* ( SFAS 149 ). SFAS 149 amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts. This standard is effective for contracts entered into or modified after June 30, 2003. The Company adopted this standard and the adoption of this standard had 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. 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. During fiscal 2004 the terms of payment on the note receivable were changed to a quarterly payment of \$50,000 and interest. As a result of the sale, the operations of WellCheck have been accounted for as discontinued operations in accordance with SFAS 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.

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

	March 26, 2004	March 28, 2003	March 29, 2002
Revenue	\$	\$ 1,472	\$ 5,619
Income (loss) before provision for income taxes	56	(1,489)	(1,356)
Income tax benefit (cost)	(22)	112	54
	<u>          </u>	<u>          </u>	<u>          </u>
Net gain (loss)	\$ 34	\$(1,377)	\$(1,302)
	<u>          </u>	<u>          </u>	<u>          </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 in fiscal 2003. The components of the loss are as follows (in thousands):

	March 28, 2003
Net book value of WellCheck assets and costs related to the sale	\$1,552
Net book value of goodwill associated with WellCheck	3,143
Less note receivable	(250)
	<u>          </u>
Net loss	\$4,445
	<u>          </u>

**3. Balance Sheet Composition**

Accounts receivable consist of (in thousands), net:

	March 26, 2004	March 28, 2003
Accounts receivable	\$6,268	\$5,376
Less allowance for sales returns		(5)
Less allowance for doubtful accounts	(230)	(176)
	<u>          </u>	<u>          </u>
	\$6,038	\$5,195
	<u>          </u>	<u>          </u>

Inventories consist of (in thousands), net:

	March 26, 2004	March 28, 2003
Raw materials	\$1,954	\$2,388
Work-in-progress	1,767	1,762
Finished goods	2,362	2,656
	<u>          </u>	<u>          </u>
	\$6,083	\$6,806
	<u>          </u>	<u>          </u>





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

	March 26, 2004	March 28, 2003
Machinery and equipment	\$ 14,514	\$ 14,149
Furniture and fixtures	471	416
Computer equipment	2,766	2,075
Leasehold improvements	2,850	2,261
Patents	111	111
Construction-in-progress	566	153
	<u>21,278</u>	<u>19,165</u>
Less accumulated depreciation and amortization	(13,021)	(11,674)
	<u>\$ 8,257</u>	<u>\$ 7,491</u>

Depreciation and amortization expense of \$2.7 million was incurred in fiscal 2004, \$2.6 million in fiscal 2003 and \$2.6 million in fiscal 2002.

All goodwill was related to WellCheck, which the Company sold in December 2002. At the time of the sale of WellCheck the net book value of goodwill was \$3.1 million, all of which was expensed as part of the sale.

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

	March 26, 2004	March 28, 2003
Trade accounts payable	\$ 1,466	\$ 2,518
Accrued accounting and reporting	405	379
Accrued royalties	666	274
Accrued legal expenses	172	261
Accrued rent	186	165
Accrued income tax		139
Accrued distributor incentives		69
Other accrued liabilities	254	166
	<u>\$ 3,149</u>	<u>\$ 3,971</u>

**4. Borrowing Arrangements**

In July 2003, the Company entered into an agreement with its primary bank for a \$4 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 September 1, 2004. As of

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March 26, 2004 and March 28, 2003, there were no borrowings outstanding under the line of credit and there was no amount reserved as a compensating balance.

**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 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. Rent expense was \$1.2 million, \$1.3 million and \$765,000 for fiscal 2004 2003 and 2002, 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 as of March 26, 2004 were \$1.0 million, \$1.1 million and \$1.1 million for fiscal 2005, 2006 and 2007, respectively.

*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 the Company in the Commercial Court in Leuven, Belgium (No. B/02/00044), 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. At the introductory hearing on April 1, 2003, the case was sent to the general docket and there have been no further developments. The Company believes this claim is without merit and intends to continue to defend the claim vigorously.

On March 14, 2003, the Company initiated trademark infringement proceedings against Euromedix before the President of the Commercial Court in Leuven, Belgium (No. BRK/03/00017), seeking in principle an order (i) to prohibit Euromedix from selling, stocking, importing, exporting or promoting in the European Economic Area (EEA) products that violate the Company's trademarks, under a penalty of 10,000 Euros for each LDX-Analyzer sold, a penalty of 1,000 Euros for each cassette sold contrary to the prohibition and a 25,000 Euros penalty for each publicity of advertisement; (ii) to prohibit Euromedix from using certain slogans and phrases, in combination with products associated with certain of the Company's trademarks, in trade documents or other announcements, under a penalty of 25,000 Euros for each document used contrary to this prohibition; and (iii) to order the destruction of the inventory of products held by Euromedix that violate the Company's trademarks, which have been imported into the EEA without the Company's permission.

A hearing was held on April 29, 2003 regarding certain procedural issues. In a judgment rendered on May 27, 2003, the Judge of Seizures of the Court of First Instance referred the complaint to the Constitutional Court before rendering a final decision. The Judge of Seizures asked the Constitutional Court to render an opinion regarding certain constitutional issues related to the trademark infringement arguments the Company raised at the hearing. Hearings in the Constitutional Court were held on July 8, 2003 and September 9, 2003. On March 24, 2004, the Constitutional Court issued its judgment which

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supported the Company's claims. The Company is currently taking steps to continue the proceedings before the Judge of Seizures and the Commercial Court.

On March 26, 2004, a putative class action lawsuit captioned *Northshore Dermatology Center, S.C. v. Cholestech Corporation, and Does 1-10*, Case No. 04CH05342, was filed in the Circuit Court of Cook County, Illinois. The Company was served with the complaint and summons on March 31, 2004. The complaint alleges that the Company violated the federal Telephone Consumer Protection Act and various Illinois state laws by sending unsolicited advertisements via facsimile transmission to residents of Illinois. The complaint seeks class certification and statutory damages of \$500 to \$1,500 each on behalf of a class that would include all residents of Illinois who received an unsolicited facsimile advertisement from the Company. To date, the Company has not responded to the complaint. The Company believes this claim is without merit and intends to defend the claim vigorously. The ultimate outcome of this matter cannot presently be determined. The liability that could potentially result from a negative outcome cannot be reasonably presently estimated but could be material to the financial position or results of operations of the Company.

On December 19, 2003, the Company entered into a settlement agreement and license agreement with Roche Diagnostics Corporation and Roche Diagnostics GmbH (Roche) in connection with ongoing patent infringement litigation. The settlement, which serves as the basis for the dismissal of all patent litigation between the parties on a worldwide basis, provides for the Company to make a \$7 million payment to Roche, which the Company made on December 30, 2003. In addition, Roche agreed to grant an irrevocable, non-exclusive, worldwide license to the Company for its patents related to HDL cholesterol. As a part of this settlement, the Company will pay Roche an ongoing royalty that will be applied to only the HDL portion of cholesterol test cassettes sold by the Company. Additionally the settlement agreement provides a mechanism for resolving any future patent infringement disputes. The Company believes that any such dispute resolution will confirm that its new HDL cholesterol test cassette, currently under development, does not infringe Roche's patents. If however, upon the resolution of any such dispute it is ultimately determined that the Company's new HDL cholesterol test cassette is covered by Roche's patents, the Company will pay the same ongoing royalty. The parties have been in litigation in the United States District Court for the Southern District of Indiana, Germany, Belgium, Switzerland and Austria. Motions to dismiss have been filed in each of these jurisdictions in connection with the settlement. The one-time payment to Roche associated with this settlement agreement, along with legal and related expenses, is included as an expense in the Company's Consolidated Statements of Operations.

The Company are also 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 financial statements.

## **6. Restructuring Accruals**

During the 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 the 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 Company's consolidated balance sheets as a part

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of accrued payroll and benefits. During fiscal 2004, the Company made payments of \$178,000 to employees terminated under the fiscal 2003 restructuring plan. As of March 26, 2004, the Company expected to make approximately \$346,000 in remaining payments in fiscal 2005 under the restructuring plan.

**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 26, 2004, nor was there any activity relating to preferred stock during the three year period ended March 26, 2004.

*Stock incentive program*

In 1997 and 2000 the shareholders approved Stock Incentive Programs for the issuance of incentive stock options ( ISOs ) and non-qualified stock options ( NSOs ) and in 1999 the Company approved NSOs as follows:

	<b>1997 Stock Incentive Program</b>	<b>1999 Nonstatutory Stock Option Program</b>	<b>2000 Stock Incentive Program</b>
Exercise price	Not less than 100% of fair market value on date of grant	Not less than 100% of fair market value on date of grant	Not less than 100% of fair market value on date of grant
Exercise period	Not to exceed 7 years and a day	Not to exceed 10 years and a day	Not to exceed 10 years and a day
Vesting period per year	25%-100%	25%-100%	25%-100%
Type of options available	ISOs / NSOs	NSOs	ISOs / NSOs
Shares of common stock reserved	900,000	2,000,000	1,845,000
Share available for future grant as of March 26, 2004	73,556	287,002	762,254

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Stock option activity under the 1997 program, 1999 program and 2000 program is as follows:

	Outstanding Options	Weighted Average Exercise Price Per Share
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
Balance, March 29, 2002	2,488,165	8.88
Granted	615,200	10.38
Exercised	(438,823)	6.45
Canceled	(259,820)	12.02
Balance, March 28, 2003	2,404,722	9.37
Granted	577,250	8.76
Exercised	(311,001)	5.10
Canceled	(310,307)	11.58
Balance, March 26, 2004	2,360,664	9.49

The following table summarizes information about stock options outstanding as of March 26, 2004:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number	Weighted Avg. Contractual Life(1)	Weighted Avg. Exercise Price	Number	Weighted Avg. Exercise Price
\$ 2.00 \$ 7.54	620,258	5.9	\$ 6.22	430,486	\$ 6.14
\$ 7.75 \$ 8.29	683,049	7.1	8.03	387,987	7.91
\$ 8.40 \$ 9.15	530,316	6.7	8.72	90,159	9.07
\$11.88 \$17.85	527,041	7.9	16.00	275,393	15.77
	2,360,664	6.9	9.49	1,184,025	9.18

(1) years

**Employee stock purchase plan**

In August 2002, the shareholders approved the 2002 Employee Stock Purchase Plan (the ESPP) which reserved 400,000 shares of common stock to be issued in accordance with the Internal Revenue Code under such terms as approved by the board of directors. 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

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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 85,521 and 40,920 shares of common stock to employees in fiscal 2004 and fiscal 2003, respectively.

*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.

*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.

*Authorized but unissued stock*

As a result of the reacquiring of the shares from the former executive, we currently have 13,425 shares of authorized but unissued stock valued at \$176,000. We have no formal stock buyback program and no other commitments to repurchase any additional shares of stock. There are no restrictions on by the state of California on the use authorized but unissued shares.

**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 \$12,000 per year during calendar year 2003, up from \$11,000 in prior year, and employees over 50 years of age may elect to contribute an additional \$2,000 (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 non-forfeitable 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 \$209,000, \$0 and \$620,000 in fiscal 2004, 2003 and 2002, respectively.

**Table of Contents****9. Income Taxes**

The provision for income taxes consisted of (in thousands):

	Federal	State	Total
<b>Year ended March 26, 2004</b>			
Current	\$	\$ 225	\$ 225
Deferred	(10,217)	(1,209)	(11,426)
Total	\$(10,217)	\$ (984)	\$(11,201)
<b>Year ended March 28, 2003</b>			
Current	\$ 266	\$	\$ 266
Deferred	(4,200)		(4,200)
Total	\$ (3,934)	\$	\$ (3,934)
<b>Year ended March 29, 2002</b>			
Current	\$ 145	\$ 144	\$ 289
Deferred			
Total	\$ 145	\$ 144	\$ 289

The differences between the federal statutory income tax rate and the Company's effective tax rate for fiscal 2004 and 2003 are as follows:

Fiscal Year Ended	March 26, 2004	March 28, 2003	March 29, 2002
Provision at statutory rate	34.0%	34.0%	34.0%
State taxes, net of federal benefit	3.2	5.8	5.8
Stock options		(8.5)	(10.2)
State tax rate change	26.2		
Utilization of research and development credits	3.0	(62.4)	
Change in valuation allowance	428.4	(495.8)	
Alternative minimum tax	(0.6)	12.9	
Valuation allowance - current		8.0	(26.4)
Other	(42.0)	28.7	0.8
	452.2%	(477.3)%	(4.0)%

The difference between the federal statutory income tax rate and the Company's effective tax rate for fiscal 2004 and 2003 relates primarily to changes in the valuation allowance for which a benefit was recognized. 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.

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Deferred tax assets and liabilities are recognized for the future tax consequences of differences between the carrying amounts of assets and liabilities and their respective tax bases using enacted tax rates in effect for the year in which the differences are expected to reverse. Significant deferred tax assets and liabilities consist of the following (in thousands):

	March 26, 2004	March 28, 2003	March 29, 2002
Net operating loss carryforwards	\$ 14,570	\$ 11,491	\$ 12,708
Research and development tax credit carryforwards	1,450	2,240	2,214
Minimum tax credit carryforwards	291	56	95
Capitalized research and development	919	948	786
Other	105	57	1,610
Valuation allowance for deferred tax assets		(10,592)	(17,413)
	<u>          </u>	<u>          </u>	<u>          </u>
	\$ 17,335	\$ 4,200	\$
	<u>          </u>	<u>          </u>	<u>          </u>

The Company has historically experienced significant operating losses and operates in an industry subject to rapid technological changes. Therefore, at March 29, 2002, the Company provided a full valuation allowance on its deferred tax assets because of uncertainty regarding its ability to generate future taxable income and the realizability of the deferred tax assets. In 2003, the Company recorded a benefit of \$4.2 million from the partial reversal of its valuation allowance. Based on improved operating performance, the Company determined that a reduction of the valuation allowance was appropriate based on estimated taxable income through 2005 of approximately \$14.6 million. In 2004, the Company recorded an additional benefit of \$10.2 million from the reversal of the remaining portion of its valuation allowance. At that time, the Company determined that it is more likely than not that all deferred tax assets will be realized in the foreseeable future based upon its projected taxable income.

The realizability of the deferred tax assets is primarily dependent on the ability of the Company to generate income in the future. Subsequent changes in the Company's estimate of future profitability could require the Company to change its estimate of the realizability of its deferred tax assets and record a valuation allowance. Such a change in estimate would result in a material deferred tax expense in the period of change.

As of March 26, 2004, the Company had net operating loss carryforwards available to reduce future taxable income through 2023 for federal tax purposes of approximately \$42.9 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 \$2.3 million and \$972,000, respectively.

As a result of a change in ownership (for tax purposes) which occurred in fiscal 1991, the Company has 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.



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**10. Segment Information**

On December 23, 2002, the Company completed the sale of certain assets and the assignment of certain obligations of WellCheck. Prior to the sale, WellCheck was one of the Company's two reportable segments. The Company now operates its business in one segment, Diagnostic Products.

**11. Other Operating Expenses**

In fiscal year 2004, other operating costs were \$250,000. The Company had no corresponding costs in fiscal year 2003. These costs related to the write-off of an option to purchase a patent, which the Company determined no longer had an economic value.

**12. Geographic Information**

All of the Company's products are similar in nature, have similar production processes, are subject to the same regulatory environment and are sold by the Company's sales professionals to companies that distribute healthcare products to end users of such products. Sales of products to distributors are made throughout the United States, Europe and Asia. Cholestech has determined that it has only one class of similar products.

The Company's export sales were \$7.4 million, \$6.6 million and \$8.0 million fiscal 2004, 2003 and 2002, respectively. Sales to Europe were \$4.1 million, \$4.4 million and \$6.4 million in fiscal 2004, 2003 and 2002, 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**

	<b>Balance at Beginning of Period</b>	<b>Additions to Costs &amp; Expenses</b>	<b>Deductions</b>	<b>Balance at End of Period</b>
<b>Fiscal Year Ended March 29, 2002</b>				
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
<b>Fiscal Year Ended March 28, 2003</b>				
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
<b>Fiscal Year Ended March 26, 2004</b>				
Allowance for doubtful accounts	\$ 176,000	\$ 59,000	\$ 45,000	\$ 230,000
Allowance for sales returns	5,000	(5,000)		
Inventory reserve	173,000	651,000		824,000

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.

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**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
10.17.9(6)	Revolving Line of Credit Note effective July 1, 2003 by and between Wells Fargo Bank and Registrant
10.20(7)	1997 Stock Incentive Program, as amended, and form of agreement thereto
10.21(8)	1999 Nonstatutory Stock Option Plan, as amended, and form of agreement thereto
10.25(9)	Employment Agreement between Registrant and Thomas E. Worthy dated August 6, 1999
10.26(9)	Employment Agreement between Registrant and Terry L. Wassmann dated March 28, 2000
10.29(10)	2000 Stock Incentive Program, as amended, and form of agreement thereto
10.32(11)	Employment Agreement between Registrant and William W. Burke dated March 14, 2001
10.37(12)	Lease Agreement between Registrant and the BIV Group dated July 23, 2001
10.38(13)	2002 Employee Stock Purchase Plan and form of agreement thereto
10.39(14)	Stock Purchase Agreement dated December 23, 2002 between Registrant, WellCheck Inc. and ImpactHealth.com, Inc.
10.40(15)	Amended and Restated Severance Arrangement between Registrant and Warren E. Pinckert II dated June 14, 2001
10.40.1(15)	First Amendment to Amended and Restated Severance Arrangement between Registrant and Warren E. Pinckert II dated March 27, 2003
10.41(15)	Change of Control Severance Agreement between Registrant and Warren E. Pinckert II dated June 14, 2001
10.41.1(15)	First Amendment to Change of Control Severance Agreement between Registrant and Warren E. Pinckert II dated January 23, 2003
10.41.2	Amended and Restated Change of Control Severance Agreement between Registrant and Warren E. Pinckert II dated March 25, 2004
10.42(15)	Severance Agreement between Registrant and William W. Burke dated July 17, 2001
10.43(15)	Change of Control Severance Agreement between Registrant and William W. Burke dated July 21, 2001
10.43.1(15)	First Amendment to Change of Control Severance Agreement between Registrant and William W. Burke dated January 23, 2003
10.43.2	Amended and Restated Change of Control Severance Agreement between Registrant and William W. Burke dated March 25, 2004
10.46(15)	Severance Agreement between Registrant and Terry L. Wassmann dated July 17, 2001

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10.46.1(15)	First Amendment to Severance Agreement between Registrant and Terry L. Wassmann dated January 23, 2003
10.47(15)	Change of Control Severance Agreement between Registrant and Terry L. Wassmann dated January 23, 2003
10.47.1(15)	First Amendment to Change of Control Severance Agreement between Registrant and Terry L. Wassmann dated January 23, 2003
10.47.2	Amended and Restated Change of Control Severance Agreement between Registrant and Terry L. Wassmann dated March 25, 2004
10.48(15)	Severance Agreement between Registrant and Thomas E. Worthy dated July 19, 2001
10.48.1(16)	First Amendment to Severance Agreement between Registrant and Thomas E. Worthy dated October 10, 2003
10.50(15)	Employment Agreement between Registrant and Donald P. Wood dated March 31, 2003
10.51(15)	Severance Agreement between Registrant and Donald P. Wood dated April 1, 2003
10.51.1(16)	First Amendment to Severance Agreement between Registrant and Donald P. Wood dated October 10, 2003
10.52(16)	Change of Control Severance Agreement between Registrant and Donald P. Wood dated October 10, 2003
10.52.1	Amended and Restated Change of Control Severance Agreement between Registrant and Donald P. Wood dated March 25, 2004
10.54(16)	Change of Control Severance Agreement between Registrant and Thomas E. Worthy dated October 10, 2003
10.54.1	Amended and Restated Change of Control Severance Agreement between Registrant and Thomas E. Worthy dated March 25, 2004
10.55	Change of Control Severance Agreement between Registrant and Kenneth F. Miller dated June 2, 2004
23.1	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (see page 65)
31.1	Certification of Chief Executive Officer under Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended
31.2	Certification of Chief Financial Officer under Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended
32	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. 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.

(6) Incorporated by reference to exhibit filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended June 27, 2003.

(7) 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.

(8) 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.

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- (9) Incorporated by reference to exhibits filed with Registrant's Annual Report on Form 10-K for the fiscal year ended March 31, 2000.
- (10) Incorporated by reference to exhibit filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended September 26, 2003.
- (11) Incorporated by reference to exhibits filed with Registrant's Annual Report on Form 10-K for the fiscal year ended March 30, 2001.
- (12) Incorporated by reference to exhibits filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended September 28, 2001.
- (13) 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.
- (14) 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.
- (15) Incorporated by reference to exhibits filed with Registrant's Annual Report on Form 10-K for the fiscal year ended March 28, 2003.
- (16) Incorporated by reference to exhibit filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended December 26, 2003.