

CHOLESTECH CORPORATION

Form 10-K

June 08, 2005

Table of Contents

**United States**  
**Securities and Exchange Commission**  
Washington, D.C. 20549  
**FORM 10-K**

(Mark One)

☐ Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
for the fiscal year ended March 25, 2005  
or

☐ Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
for the transition period from to

Commission File Number: 000-20198

**CHOLESTECH CORPORATION**

(Exact name of registrant as specified in its charter)

**CALIFORNIA**

(State or other jurisdiction of  
incorporation or organization)

**3347 INVESTMENT BOULEVARD**

**HAYWARD, CALIFORNIA**

(Address of principal executive offices)

**94-3065493**

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

**94545**

(Zip Code)

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

Securities registered pursuant to Section 12(b) of the Act: **None**

Securities registered pursuant to Section 12(g) of the Act:

**COMMON STOCK, NO PAR VALUE**

**SERIES A PARTICIPATING PREFERRED STOCK, NO PAR VALUE**

(Title of Class)

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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

The aggregate market value of the voting stock held by non-affiliates of the registrant, based on the closing sale price of the common stock on September 24, 2004 as reported on the NASDAQ National Market, was approximately \$75,964,000. Shares of common stock held by each executive officer and director and by each person who owns 5% or more of the outstanding common stock have been excluded from this computation. This determination of affiliate status is not necessarily a conclusive determination for other purposes. The registrant does not have any non-voting stock.

As of May 31, 2005, the registrant had outstanding 14,648,713 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 2005 Annual Meeting of Shareholders to be held August 17, 2005.

Cholestech Corporation  
Annual Report on Form 10-K  
For The Fiscal Year Ended March 25, 2005  
Table of Contents

PART I

<u>Item 1.</u>	<u>Business</u>	2
<u>Item 2.</u>	<u>Properties</u>	20
<u>Item 3.</u>	<u>Legal Proceedings</u>	20
<u>Item 4.</u>	<u>Submission of Matters to a Vote of Security Holders</u>	22

PART II

<u>Item 5.</u>	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	23
<u>Item 6.</u>	<u>Selected Consolidated Financial Data</u>	23
<u>Item 7.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	25
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	52
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>	53
<u>Item 9.</u>	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	53
<u>Item 9A.</u>	<u>Controls and Procedures</u>	53
<u>Item 9B.</u>	<u>Other Information</u>	54

PART III

<u>Item 10.</u>	<u>Directors and Executive Officers of the Registrant</u>	54
<u>Item 11.</u>	<u>Executive Compensation</u>	54
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	54
<u>Item 13.</u>	<u>Certain Relationships and Related Transactions</u>	54
<u>Item 14.</u>	<u>Principal Accountant Fees and Services</u>	54

PART IV

<u>Item 15.</u>	<u>Exhibits and Financial Statement Schedules</u>	55
	<u>Signatures</u>	59
<u>EXHIBIT 10.29.1</u>		
<u>EXHIBIT 23.1</u>		
<u>EXHIBIT 31.1</u>		
<u>EXHIBIT 31.2</u>		
<u>EXHIBIT 32</u>		

**Table of Contents**

**Part I**

*Some of the statements contained in this Annual Report on Form 10-K are forward-looking statements about Cholestech Corporation ( we, us or Cholestech ), including but not limited to those specifically identified as such, that involve risks and uncertainties. The statements contained in the Report on Form 10-K that are not purely historical are forward looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, including, without limitation, statements regarding our expectations, beliefs, intentions or strategies regarding the future. All forward-looking statements included in this Report on Form 10-K are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors, which may cause our actual results to differ materially from those implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as may, will, should, expects, plans, anticipates, 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 38 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 2005, 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.

2

**Table of Contents**

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. 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 for 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 104,000 sites operated by physicians or groups of physicians that are registered with the Centers for Medicare & Medicaid Services ( CMS ), approximately 51,000 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 27% since 2000.

Sales of our products to international markets represented 14% of our revenue in fiscal year 2005. While a majority of such sales are in Europe, we are expanding into Asia, and South America. See Note 10 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 25, 2005. 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 beginning January 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.

**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 \$244 billion.

**Table of Contents**

The American Heart Association estimates that more than 70 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%. NIH guidelines continue to encourage the increase of cholesterol testing as the recommended LDL levels decreased from 100 to 80 in 2004.

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:

*Leverage Our Installed Base.* We intend to leverage our installed base of LDX systems in each customer location by adding new test cassettes to our current testing platform and offering new products which increase the amount and frequency of testing. Our current research and development efforts include the planned introduction of new test cassettes for high sensitivity C-Reactive Protein ( hs-CRP ) and lipid profile/alanine aminotransferase ( 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 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.

## Table of Contents

### 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 rapidly 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 \$4.3 million, \$3.2 million and \$2.7 million for fiscal years 2005, 2004 and 2003, respectively.

#### *Overview of the Cholestech LDX System*

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

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

The LDX System includes software that performs cardiac risk assessments using risk factor parameters developed from the Framingham study, a long term study of cholesterol levels and cardiovascular disease. A risk assessment is required by the NIH guidelines.

#### *The LDX Analyzer*

Revenue from the LDX Analyzer represented 6%, 8% and 9% of total revenue in fiscal years 2005, 2004 and 2003, respectively. The LDX Analyzer is a proprietary, four-channel, reflectance photometer that measures

## **Table of Contents**

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 \$2,055.

### *Cassette Products*

Revenue from cassette products represented 83%, 81% and 79% of total revenue in fiscal years 2005, 2004 and 2003, respectively. Our line of single-use, disposable test cassettes for the LDX System incorporates patented and licensed technology for distributing precisely measured plasma to up to four reaction pads for simultaneous testing. Each cassette has three parts: a main body that contains the sample well into which the blood sample is dispensed, a reaction bar where plasma is transferred for analysis and a magnetic strip encoded with test instructions and lot specific calibration information for the various chemistries on the reaction pads. Capillary action draws a drop of blood through a separation medium within the cassette, stopping the cellular components of the blood while transferring a small volume of plasma to the cassette's reaction pads. When the plasma contacts the reaction pads, the dry chemistry reacts with the analytes in the plasma, producing color. The intensity of color developed indicates the concentration of the analytes in the plasma. The magnetic strip contains information needed by the LDX Analyzer to convert the reflected color reading into a concentration level for the accurate measurement of the analytes being tested. As a result of this automatic process, the healthcare provider does not have to interpret any color reaction, relate a reading to a separate chart or input calibration information. Our available test cassettes range in current domestic list price from \$4.07 to \$11.59 per cassette and include up to six results per cassette.

### *Overview of the Cholestech GDX System*

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

### *The GDX Analyzer*

The GDX Analyzer uses a photometer that measures the amount of light transmitted through the reaction solutions and incorporates a microprocessor with built-in software. The GDX Analyzer contains a receptacle for insertion of the cartridge, three buttons for user activation and a liquid crystal display to present user-



**Table of Contents**

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.

***Cartridge Product***

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

**Table of Contents**

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

<b>Product</b>	<b>Regulatory Status (1)</b>
<b>Instrument</b>	
LDX Analyzer	FDA cleared; CLIA waived
GDX Analyzer	FDA cleared, CLIA waived
Endo-PAT	510(k) 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)/ Aspartate Aminotransferase (AST)	FDA cleared, CLIA waived
<i>Under Development (2)</i>	
High Sensitivity C-Reactive Protein (HS-CRP)	510(k) cleared
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
Creatine Kinase (CK)	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 market clearance pursuant to Section 510(k) of the Food, Drug and Cosmetics Act of 1938, as amended. CLIA waived means the Food and Drug Administration has granted our application to classify the product as having waived status with respect to the Clinical Laboratory Improvement Amendments.

(2) Products under development are those that have completed the feasibility phase of the commercialization process and have begun the development phase. During the development phase, manufacturing processes are developed and defined, initial lots are made using those manufacturing processes and performance against product specifications is demonstrated. The products under development are then transferred to manufacturing prior to

launch.

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

*Current Cassette and Cartridge Products*

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

8

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## **Table of Contents**

*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 and Aspartate Aminotransferase.* Patients undergoing certain drug therapies must be monitored for increases in certain enzymes that are associated with liver damage. The alanine and aspartate aminotransferase ( ALT/ AST ) 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.

*High Sensitivity C-Reactive Protein.* The hs-CRP test measures, by immunoassay, the amount of CRP present in a patient sample. Recent research has demonstrated that CRP is a systemic marker of

## Table of Contents

inflammation and the measurement of CRP is useful in the detection and evaluation of infection, tissue injury, inflammatory disorders, and associated diseases. Studies have shown that CRP is an independent risk factor for coronary heart disease and when used in conjunction with certain other risk factors, such as total cholesterol and HDL-cholesterol, is useful in predicting future cardiovascular events. We expect the hs-CRP test to be available in the summer of 2005.

*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. We expect this product to be available in late calendar year 2005.

### *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.

#### *Liver Panel*

*ALT/AST.*

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

#### *Statin Safety Panel*

*ALT/AST.*

*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.

### *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 calculated LDL cholesterol is subject to a number of limitations including the need for a fasting sample. The direct LDL cholesterol test is reimbursable, whereas the calculated test is not.

*Hemoglobin 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.

**Table of Contents**

*Other Platforms*

*Vascular Endothelial Dysfunction.* The Endo-PAT is a non-invasive device that is as a diagnostic aid in the detection of coronary artery endothelial dysfunction. The endothelium is the lining of all the blood vessels and is the site of the development of coronary artery disease.

**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 products include: Physician Sales and Service, Inc., Henry Schein, Inc., McKesson Corporation, Cardinal Health, Inc., Edwards Medical Supply, and Fisher Scientific International, 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, the Endo-PAT, for assessing vascular endothelial dysfunction. Vascular disease experts recognize endothelial dysfunction as an early stage in the development of atherosclerosis.

*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 utilizing our LDX System in connection with such programs include AstraZeneca PLC and Pfizer Inc.

**SALES AND MARKETING**

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

## Table of Contents

Our sales and marketing strategy includes increasing penetration into the physician office laboratory and health promotion markets and leveraging our installed base of LDX and GDX Analyzers. We 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. In order to support this effort, over the last year we hired representatives who focus on calling our key accounts by phone. 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, Fisher Scientific, McKesson, Physician Sales and Service and Henry Schein, which together have more than 2,500 sales professionals who focus primarily on the United States physician office laboratory ( POL ) 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 whose primary focus are to provide equipment and supplies to customers that conduct diagnostic screening for cholesterol and related lipid levels and diabetes. Some of these distributors also sell to the POL market segment.

*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 35 foreign distributors to distribute the LDX System and cassettes primarily in Europe, Asia and South America.

## 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 are currently making or developing products that compete or will compete with ours. We believe we currently have a competitive advantage due to (i) the status of the

## Table of Contents

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 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 CLIA waiver.

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

### MANUFACTURING

We manufacture, test, perform quality assurance on, package and ship our products from our approximately 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, 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. All our cassette production is currently on our high volume manufacturing line. We use a second manufacturing line for research and development purposes.

*Raw Materials and Quality Assurance.* Suppliers provide us with the subassemblies, components and raw materials necessary for the manufacture of our products. These subassemblies, components and raw materials are inspected and tested by our quality control personnel. We expect the supply of raw materials to be adequate for our current level of business and into the foreseeable future. Our manufacturing facilities are subject to periodic inspection by regulatory authorities. Certain key components and raw materials used in the manufacturing of our products are currently provided by single



**Table of Contents**

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 10 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 four additional patent applications in the United States and internationally under the Patent Cooperation Treaty and individual foreign applications. We are also the licensee of United States patents relating to the measurement of Lp(a) and a portion of our cassette technology.

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

In December 2003, we and Roche Diagnostics signed a settlement agreement and a license agreement which settled and dismissed all existing patent litigation between us on a worldwide basis. 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 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 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.

## Table of Contents

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

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

Before a new device can be introduced into the market, the manufacturer must generally obtain marketing clearance through a pre-market notification under Section 510(k) of the FDC Act or a pre-market approval application under Section 515 of the FDC Act or be exempt from 510(k) requirements. Most Class I devices are exempt from 510(k) requirements. A 510(k) clearance typically will be granted if the submitted information establishes that the proposed device is substantially equivalent to a legally marketed Class I or II medical device or to a Class III medical device for which the FDA has not called for a pre-market approval. A 510(k) notification must contain information to support a claim of substantial equivalence, which may include laboratory test results or the results of clinical studies of the device in humans. It generally takes from four to 12 months from the date of submission to obtain 510(k) clearance, but it may take longer. A not substantially equivalent determination by the FDA, or a request for additional information, could delay the market introduction of new products that fall into this category. For any devices that are cleared through the 510(k) process, modifications or enhancements that could significantly affect safety or effectiveness or constitute a major change in the intended use of the device will require new 510(k) submissions. We obtained 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 receive 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.

## **Table of Contents**

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

The FDC Act regulates our quality control and manufacturing procedures by requiring us and our contract manufacturers to demonstrate compliance with quality systems regulations. The FDA monitors compliance with these requirements by requiring manufacturers to register with the FDA, which subjects them to periodic inspections. We were recently inspected by the FDA as part of a routine quality system audit. The State of California also regulates and inspects our manufacturing facilities. We have been inspected twice by the State of California to date and are manufacturing under an issued medical device manufacturer's facility license from the State of California. If any violations of our applicable regulations are noted during a FDA, European Notified Body or State of California inspection of our manufacturing facilities or those of our contract manufacturers, the continued marketing of our products could be materially adversely affected. The European Union ( EU ) has promulgated rules that require that devices such as ours receive the right to affix the CE mark, a symbol of adherence to applicable EU directives. We have completed all the testing necessary to comply with applicable regulations to currently be eligible for self certification. While we intend to satisfy the requisite policies and procedures that will permit us to continue to affix the CE mark to our products in the future, there can be no assurance that we will be successful in meeting EU certification requirements. Failure to receive the right to affix the CE mark may prohibit us from selling our products in EU member countries and could have a material adverse effect on our business, financial condition and results of operations.

We and our products are also subject to a variety of state and local laws and regulations in those states or localities where our products are or will be marketed. Any applicable state or local laws or regulations may hinder our ability to market our products in those states or localities. For example, eight states have regulations that impose requirements on pharmacies and/or pharmacists that perform clinical testing, four of which have regulations that prohibit certain pharmacy-based testing. We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. There can be no assurance that we will not be required to incur 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 Amendments, 1988*

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 Certificate of Waiver or a registration certificate (for moderately complex testing) from CMS. Some states may require a state license also. 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

## **Table of Contents**

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 with fewer requirements and at a lower cost.

### **THIRD PARTY REIMBURSEMENT**

In the United States, healthcare providers such as hospitals and physicians that purchase products such as the LDX System and single-use test cassettes generally rely on third party payors, including private health insurance plans, federal Medicare, state Medicaid and managed care organizations, to reimburse all or part of the cost of the procedure in which the product is being used. Our ability to commercialize our products successfully in the United States will depend in part on the extent to which reimbursement for the costs of tests performed with the LDX System and related treatment will be available from government health authorities, private health insurers and other third party payors. For example, provisions for cholesterol and diabetes screening were included in the federal Prescription Drug and Medicare Improvement Act of 2003, which was implemented in January 2005. 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. 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

**Table of Contents**

to defer obtaining medical equipment as a result of any such limitation on their capital expenditures. The Medicare legislation also requires CMS to adopt uniform coverage and administration policies for laboratory tests. We are unable to predict what adverse impact on us, if any, additional government regulations, legislation or initiatives or changes by other payors affecting reimbursement or other matters that may influence decisions to obtain medical equipment may have.

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

**PRODUCT LIABILITY AND INSURANCE**

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

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 25, 2005, we employed 204 full-time associates. There were 93 employees in manufacturing, 48 employees in sales and marketing, 31 employees in administration and 32 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:

<b>Name</b>	<b>Age</b>	<b>Position</b>
Warren E. Pinckert II	61	President, Chief Executive Officer and Director
John F. Glenn	43	Vice President of Finance, Chief Financial Officer, Treasurer and Secretary
Barbara T. McAleer	47	Vice President of Quality Assurance and Regulatory Affairs
Kenneth F. Miller	49	Vice President of Sales and Marketing
Terry L. Wassmann	58	Vice President of Human Resources
Donald P. Wood	53	Vice President of Operations
Thomas E. Worthy	63	Vice President of Development

*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 PacificCare 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.

*John F. Glenn* has served as our Corporate Vice President of Finance, Chief Financial Officer, Treasurer and Secretary since October 2004. Before joining Cholestech, Mr. Glenn was Vice President of Finance and Chief Financial Officer at Invivo Corporation, a provider of monitoring systems for patients in medical settings, from 1990 to 2004. Invivo was sold to Intermagnetics General Corporation in January 2004. Mr. Glenn holds a Bachelor of Science degree in Business Administration from the University of Nevada and a Masters of Business Administration from the University of Santa Clara.

*Barbara T. McAleer* has served as our Vice President of Quality Assurance and Regulatory Affairs since February 2005. Before joining Cholestech, Ms. McAleer was a managing partner at LOL Partners, a consulting firm specializing in the healthcare industry. From January 2001 to June 2003, she was General Manager/ Vice President of Operations & Quality for Calypte Biomedical Corporation. Before joining Calypte, Ms. McAleer spent 1982 to 2000 with Johnson & Johnson in various manufacturing and quality assurance positions. Ms. McAleer holds a Bachelor of Science degree in Operations Management from Penn State University and a Masters of Business Administration from Claremont Graduate School, Peter Drucker Management Center.

*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 department,

including the

19

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## Table of Contents

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 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.cholesteck.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. 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 an approximately 69,000 square foot leased 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 2017. 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



## Table of Contents

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 for each LDX Analyzer sold, a penalty of 1,000 for each cassette sold contrary to the prohibition and a 25,000 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 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. On March 24, 2004, the Constitutional Court issued its judgment which supported our claims. A hearing was scheduled for November 9, 2004 by the Judge of Seizures of the Court of First Instance to hear additional submissions. On December 21, 2004, the Judge of Seizures of the Court of First Instance decided against Euromedix's opposition to certain procedural issues.

After the decisions of the Judge of Seizures of the Court of First Instance, we have filed requests for a procedural calendar in the three trademark infringement proceedings against Euromedix of which two are pending before the President of the Commercial Court of Leuven and one before the Commercial Court of Leuven. Both parties have exchanged submissions. All three cases are scheduled for pleadings at a hearing on June 21, 2005.

Euromedix has filed a request for a procedural calendar in the case pending before the Commercial Court of Leuven regarding the termination of the business relationship on July 11, 2002. We have to file submissions by August 18, 2005 and final submissions by October 3, 2005. The case is set for pleadings at a hearing on November 8, 2005.

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 alleged 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 sought 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 us. On January 18, 2005 the parties entered into an agreement to settle all claims on behalf of a nationwide class. Under the terms of the settlement, in March 2005 we paid \$625,000 in cash to settle all claims, \$600,000 of which was funded by

**Table of Contents**

insurance. We also agreed to pay up to \$50,000 for providing notice to the class and for processing claims. The Court granted preliminary settlement approval and a final settlement approval hearing is currently scheduled for July 11, 2005.

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.

22

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**Table of Contents**

## 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 24, 2005, the last reported sale price for our common stock on the NASDAQ National Market was \$10.00 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 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
<b>Fiscal Year 2005</b>		
First Quarter	\$ 10.29	\$ 7.20
Second Quarter	8.15	6.16
Third Quarter	8.62	6.35
Fourth Quarter	13.68	7.69

As of March 25, 2005, there were 14,614,914 shares of our common stock issued and outstanding and held by approximately 156 holders of record. We estimate that there are approximately 5,000 beneficial owners of our common stock.

**Dividend Policy**

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

**Equity Compensation Plans**

The information required by this item regarding equity compensation plans is incorporated by reference under the section entitled *Equity Compensation Plan Information* contained in our proxy statement for our 2005 annual meeting of shareholders.

**Item 6: Selected 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 25, 2005, March 26, 2004 and March 28, 2003 and the selected consolidated balance sheet data as of March 25, 2005 and March 26, 2004 are derived from, and qualified by reference to, the audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. The selected consolidated statement of operations data for the fiscal years ended March 29, 2002 and March 30, 2001 and the consolidated balance sheet data as of March 28, 2003, March 29, 2002 and March 30, 2001 have been derived from our audited consolidated financial statements not included in this Annual Report.

**Table of Contents**

These historical results are not necessarily indicative of the results of operations to be expected from any future period.

**Year Ended March 31,(1)**

**2005                      2004                      2003                      2002                      2001**

(in thousands, except per share data)

**Consolidated Statement of Operations Data:**

Revenue	\$ 52,877	\$ 52,376	\$ 48,541	\$ 41,747	\$ 32,489
Cost of revenue	21,390	23,180	20,424	17,040	14,054
Gross profit	31,487	29,196	28,117	24,707	18,435
Operating expenses:					
Sales and marketing	11,494	12,654	11,737	9,241	8,287
Research and development	4,252	3,159	2,722	2,201	2,195
General and administrative	9,864	8,153	7,008	6,447	4,293
Other operating costs		250			
Litigation and other related		7,786	307	126	1,311
Total operating expenses	25,610	32,002	21,774	18,015	16,086
Income (loss) from operations	5,877	(2,806)	6,343	6,692	2,349
Interest and other income, net	231	278	438	449	655
Income (loss) before taxes	6,108	(2,528)	6,781	7,141	3,004
Provision (benefit) for income taxes(2)	1,968	(11,201)	(3,934)	289	224
Income from continuing operations	4,140	8,673	10,715	6,852	2,780
Gain (loss) from discontinued operations	8	34	(1,377)	(1,302)	(5,386)
Loss from sale of discontinued operations			(4,445)		
Net income (loss)	\$ 4,148	\$ 8,707	\$ 4,893	\$ 5,550	\$ (2,606)
Income from continuing operations per share:					
Basic	\$ 0.29	\$ 0.62	\$ 0.79	\$ 0.54	\$ 0.23
Diluted	\$ 0.29	\$ 0.61	\$ 0.76	\$ 0.50	\$ 0.22
Income (loss) from discontinued operations per share:					
Basic	\$ 0.00	\$ 0.01	\$ (0.43)	\$ (0.10)	\$ (0.45)

Diluted	\$	0.00	\$	0.00	\$	(0.41)	\$	(0.10)	\$	(0.43)
Net income (loss) per share:										
Basic	\$	0.29	\$	0.63	\$	0.36	\$	0.44	\$	(0.22)
Diluted	\$	0.29	\$	0.61	\$	0.35	\$	0.40	\$	(0.21)
Shares used to compute net income (loss) per share(3):										
Basic		14,295		13,922		13,551		12,658		12,046
Diluted		14,472		14,235		14,077		13,730		12,416

**Table of Contents****Year Ended March 31,(1)**

	2005	2004	2003	2002	2001
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(in thousands)

**Consolidated Balance Sheet Data:**

Cash, cash equivalents and marketable securities and long term investments	\$ 33,468	\$ 23,602	\$ 26,081	\$ 22,107	\$ 12,365
Working capital	33,578	23,986	22,579	20,848	10,254
Total assets	74,121	63,230	52,012	42,751	30,742
Accumulated deficit	(24,732)	(28,880)	(37,587)	(42,480)	(48,030)
Shareholders' equity	66,592	57,278	44,728	36,721	24,858

- (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. For convenience, we have indicated in this Annual Report on Form 10-K that our fiscal year ends on March 31 and refer to the fiscal year ending March 25, 2005 as fiscal year 2005, March 26, 2004 as fiscal year 2004, March 28, 2003 as fiscal year 2003, March 29, 2002 as fiscal year 2002, and the fiscal year ending March 30, 2001 as fiscal year 2001.
- (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.

**Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations****INTRODUCTION**

Management's discussion and analysis of financial condition and results of operations, 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 operations, 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 statement 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 25, 2005.

*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.

## **Table of Contents**

*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 104,000 sites that are registered with the Centers for Medicare & Medicaid Services ( CMS ), approximately 51,000 of which are registered to perform only tests that have been waived under CLIA.

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 21 regional sales managers who coordinate and work with our distribution partners to identify and promote sales of our products. We also employ 14 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 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 in early adopter sites to further promote recognition of the product and technology while assessing United States market development needs.

In June 2004 we announced that the FDA granted 510(k) clearance for our new hs-CRP test. The new hs-CRP test cassette can be used on our existing Cholestech LDX® System once a simple software upgrade has been completed. This 510(k) clearance will allow us to market the product to moderately complex laboratories. We also plan to seek waived status from the FDA for the hs-CRP test. CRP is a systemic marker of inflammation and the measurement of CRP is useful as an aid in the detection and evaluation of infection, tissue injury, inflammatory disorders, and associated diseases. We plan to introduce hs-CRP in the summer of 2005.

In June 2004, we announced that our second liver enzyme test, AST, received the FDA waiver under the CLIA. This classification establishes our AST product as the only CLIA-waived diagnostic test for AST that healthcare providers can use to easily, reliably and conveniently assess damage to the liver due to drugs or certain diseases. The AST test will run on our LDX System, in conjunction with our ALT test, delivering results with the same precision and accuracy, in less than five minutes using a single drop of blood, as methods performed in centralized or reference labs. Combining these two tests on a



**Table of Contents**

single cassette advances our goal of offering a four-test liver function panel. We began shipping the AST product in September 2004.

In November 2004, the CMS announced the 2005 Physician Fee Schedule, which guarantees access to preventive cholesterol screenings for 39 million Medicare-eligible beneficiaries. Beginning in January of 2005, Medicare Section 612 Cardiovascular Screening coverage went into effect as part of the larger Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). All Medicare beneficiaries will have access to preventive cholesterol screening blood tests for the early detection of cardiovascular disease and all new Medicare members will be covered for an initial physical examination. Both include the use of three tests to detect early risk for cardiovascular disease, including total cholesterol, a HDL-cholesterol, and a triglycerides test, which can be ordered as a lipid panel or individually.

**RESULTS OF OPERATIONS**

In the following discussion of our results of operations, results related to WellCheck have been classified as discontinued operations .

**COMPARISON OF FISCAL YEARS ENDED MARCH 25, 2005 AND MARCH 26, 2004**

	<b>Fiscal Year Ended</b>					
	<b>March 25, 2005</b>		<b>March 26, 2004</b>		<b>Amount of Increase (Decrease)</b>	<b>Percentage Increase (Decrease)</b>
	<b>Amount</b>	<b>% of sales</b>	<b>Amount</b>	<b>% of sales</b>		
Revenue	\$ 52,877	100%	\$ 52,376	100%	\$ 501	1%
Cost of revenue	21,390	40	23,180	44	(1,790)	(8)
Gross profit	31,487	60	29,196	56	2,291	8
Operating expenses						
Sales and marketing	11,494	22	12,654	24	(1,160)	(9)
Research and development	4,252	8	3,159	6	1,093	35
General and administrative	9,864	18	8,153	16	1,711	21
Other operating costs			250		(250)	(100)
Legal and other related			7,786	15	(7,786)	(100)
Total operating expenses	25,610	48	32,002	61	(6,392)	(20)
Income (loss) from operations	5,877	11	(2,806)	(5)	8,683	309
Interest and other income, net	231		278	1	(47)	(17)
Provision (benefit) for income taxes	1,968	4	(11,201)	(21)	13,169	(118)
Income from continuing operations	4,140	8	8,673	17	(4,533)	(52)
Income from discontinued operations	8		34		(26)	(76)
Net income	\$ 4,148	8%	\$ 8,707	17%	\$ (4,559)	(52)%

*Revenue.* Our total revenue increased 1% to \$52.9 million in fiscal year 2005 from \$52.4 million in fiscal year 2004 due primarily to increased sales of single-use test cassettes, which was offset by decreased sales in the first quarter of fiscal year 2005 due to our decision to eliminate quarter end discounts on large volume purchases by its distribution partners. Revenue for our LDX analyzer decreased 18% in fiscal year 2005. The revenue decline was attributable to a promotion earlier in the year in which certain end-users were provided a free LDX when they purchased a predetermined number of single-use test cassettes from our distribution partners.

27

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**Table of Contents**

Revenue for our GDX analyzer and related single-use test cartridges decreased 33% in fiscal year 2005. The decline in GDX and related product revenue related to our decision to de-emphasize those products in order to focus on our lipid and products under development and business in light of Medicare reimbursement for cholesterol and diabetes screening, which can be performed on the LDX.

Domestic revenue for fiscal year 2005 increased \$0.6 million, or 1% to \$45.6 million from \$45.0 million in fiscal year 2004. On October 1, 2004, we increased our domestic list price for all of our LDX related products by 3%, which increased domestic LDX revenue by approximately \$750,000. Most of the increase in domestic revenue related to revenue from single-use test cassettes which increased \$1.8 million, or 5%, to \$39.1 million for fiscal year 2005 from \$37.3 million for fiscal year 2004. Revenue for the LDX analyzer decreased \$0.9 million, or 33%, to \$1.9 million for fiscal year 2005 from \$2.8 million for fiscal year 2004.

We expect domestic LDX revenue for fiscal year 2006 to increase due to the release of our new ALT/AST, hs-CRP and Lipid/ALT test cassettes and increased testing on our installed base due to the recently enacted Medicare reimbursement for the screening of lipids for the Medicare population. Additionally, domestic revenue for our GDX analyzer and related single-use test cartridges decreased \$0.6 million, or 26%, to \$1.6 million for fiscal year 2005 from \$2.2 million for fiscal year 2004. The decline in GDX and related product revenue related to our decision to de-emphasize those products in order to focus on our lipid and pending products and business in light of Medicare reimbursement for cholesterol and diabetes screening which can be performed on the LDX.

International revenue decreased 2% in fiscal year 2005 from fiscal year 2004. The decrease was primarily related to a reduction of orders from pharmaceutical companies in Latin America. International revenue is primarily to related pharmaceutical promotional programs which tend to occur in irregular patterns and are difficult to forecast. Most of the decline related to the sale of single-use test cassettes, which decreased 3% in fiscal year 2005. This was offset by LDX revenue which increased 21% for the same period. Additionally, international revenue for our GDX and related products decreased 57% in fiscal year 2005.

*Cost of Revenue.* Cost of revenue includes direct labor, direct material, overhead and royalties. Our cost of revenue decreased \$1.8 million, or 8%, to \$21.4 million in fiscal year 2005 from \$23.2 million in fiscal year 2004. As a percentage of sales, the gross margins were 60% and 56% for fiscal year 2005 and fiscal year 2004, respectively. The improvement in gross margin related to the shift in product mix toward single-use cassettes, which are our highest margin products. Factory spending decreased 2% for fiscal year 2005 compared to fiscal year 2004. In addition, inventory scrap decreased by \$1.0 million due to improvements in the manufacturing process and controls, which improved the yield during the production of single-use test cassettes. A 3% price increase on domestic LDX and related products, increased margins by approximately \$750,000 or 1%. During fiscal year 2006, 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 cost control.

We have licensed certain technology used in some of our products. One ongoing royalty agreement, which expires in March 2006, requires us to pay a royalty of 2% 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 applies to only the HDL portion of cholesterol test cassettes we sell. This agreement was effective as of December 1, 2003 and expires on December 3, 2013. Royalty spending in fiscal year 2005 increased by \$1 million, or 80%, from fiscal year 2004 due to the agreement with Roche relating to HDL products.

Royalty payments are charged to cost of revenue as incurred.

28

**Table of Contents**

*Operating Expenses*

*Sales and Marketing.* Sales and marketing expenses include salaries, commissions, bonuses, travel and expenses for outside services related to marketing programs. Sales and marketing expenses decreased \$1.2 million, or 9%, to \$11.5 million for fiscal year 2005 from \$12.7 million for fiscal year 2004. A decline of \$1.3 million in product marketing expenses, including product sample, advertising and market research, was the primary reason for the decrease. Additionally, travel costs decreased by \$337,000. This was partially offset by wages, commissions and related costs which increased by \$479,000 and employee costs, including recruiting and relocation, which increased by \$225,000. As a percent of total revenue, sales and marketing expenses were 22% and 24% for fiscal year 2005 and fiscal year 2004, respectively. We expect that our sales and marketing costs will remain constant as a percentage of revenue in fiscal year 2006.

*Research and Development.* Research and development expenses include salaries, bonuses, professional consulting service expenses, supplies and depreciation of capital equipment. Research and development expenses increased \$1.1 million, or 35%, to \$4.3 million for fiscal year 2005 from \$3.2 million for fiscal year 2004. The increased spending related primarily to higher headcount and associated wages, benefits and allocated facilities, which were connected to new product development. Outside consultants costs related to new product development also increased. As a percent of total revenue, research and development expenses increased to 8% for fiscal year 2005 from 6% for fiscal year 2004. We expect our research and development costs to increase as a percentage of revenue during fiscal year 2006 as we prepare new products for the marketplace.

*General and Administrative.* General and administrative expenses include compensation, benefits and expenses for outside professional services, including information services, legal and accounting. General and administrative expenses increased \$1.7 million, or 21%, to \$9.9 million for fiscal year 2005 from \$8.2 million for fiscal year 2004. This increase was primarily attributable to a \$836,000 increase in costs associated with outside professional services and consulting, including accounting support, which primarily related to compliance cost for the Sarbanes-Oxley Act of 2002. Additionally, bonuses and other benefit related costs increased \$1.2 million relating to obtaining management goals, higher benefit cost structure and increased headcount. This increase was offset by lower insurance premiums including directors and officers liability insurance premiums, which decreased \$328,000. As a percent of total revenue, general and administrative expenses increased to 19% for fiscal year 2005 from 16% for fiscal year 2004. We expect our general and administrative costs will decrease as a percentage of revenue in fiscal year 2006.

*Other Operating Costs.* For fiscal year 2004, other operating costs were \$250,000, with no corresponding costs for fiscal year 2005. This cost 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 litigation and other related expenses included professional consulting fees, court related costs and other fees relating to Roche litigation. These costs were \$7.8 million in fiscal year 2004 with no corresponding expense in fiscal year 2005. These costs are 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 and other income, net reflects income from the investment of cash balances and marketable securities, net of expenses. Interest income decreased 17% to \$231,000 in fiscal year 2005 from \$278,000 in fiscal 2004. Loss from the sale of marketable securities was \$18,000

**Table of Contents**

during fiscal year 2005 compared to a gain of \$121,000 in fiscal year 2004. We expect income from marketable securities to remain constant unless there is a change in the market yield on corporate bonds or use of investments.

*Income Taxes.* For fiscal year 2005, we recorded a provision for income taxes of \$2.0 million for an effective tax rate of 32.2%. The effective tax rate is less than the applicable federal and state tax rates due to a benefit relating to California manufacturers' investment credit and research and development credits. The income tax benefit of \$11.2 million recorded in fiscal year 2004, primarily related to the release of the valuation allowance previously established for our net operating losses. We expect to use net operating loss carryforwards ( NOL ) and other tax carryforwards to the extent taxable income is earned in fiscal year 2006 and beyond. As of March 25, 2005, we had NOL carryforwards of \$42.6 million available to reduce future taxable income for federal income tax purposes and \$2.7 million for state tax purposes.

Ownership changes, as defined under Section 382 of the Internal Revenue Code, have occurred. As a result, the annual limitation on utilization of net operating losses generated prior to December 16, 1992 is approximately \$5.7 million. We expect that this annual limitation will not cause any of the net operating losses to expire prior to utilization.

*Discontinued Operations.* Discontinued operations in 2005 and 2004 includes TEAMS royalty revenue sold to Impact Health upon the sale of Wellcheck. Income from discontinued operations decreased 76% to \$8,000 in fiscal year 2005 from income of \$34,000 in 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, as a component of discontinued operations.

COMPARISON OF FISCAL YEARS ENDED MARCH 26, 2004 AND MARCH 28, 2003

	Fiscal Year Ended					
	March 26, 2004			March 28, 2003		
	Amount	% of sales	Amount	% of sales	Amount of Increase (Decrease)	Percentage Increase (Decrease)
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)	19

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%

30

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## **Table of Contents**

*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. This increase 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.

International revenue increased 12% during fiscal year 2004 over fiscal year 2003. Revenue for single-use cassettes increased 10% while unit volume 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.

Revenue for the GDX Analyzer and single use test cartridges increased 15% during 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.

*Cost of Revenue.* Cost of revenue includes direct labor, direct material, overhead and royalties. Our cost of revenue increased 13% to \$23.2 million for fiscal year 2004 from \$20.4 million for fiscal year 2003. The increase in cost of revenue related primarily to additional products shipped in support of the 8% increase in revenue during fiscal year 2004 over the prior fiscal year. Additionally, expenses associated with promotional programs tied to revenue increased in fiscal year 2004. Factory spending increased 17% during 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.

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% on net sales of all single use test cassettes. In December 2003, as part of a settlement agreement with Roche, we entered into another royalty agreement that is 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 from \$11.7 million for fiscal year 2003. The increase in wages and related and travel reflects a full year impact of increase in staffing related to providing additional technical service support to our installed base which was expanded late in fiscal year 2003, and severance accrual for our former Vice President of Sales and Marketing. The increase in outside services is related to market research and expenses related to industry specific public relations initiatives. Product marketing expenses decreased primarily due to fewer free 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.

## Table of Contents

*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 is 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 2003. Insurance costs increased due to the additional policy premiums for director's and officer's insurance. Outside service expenses increased due to larger expenditures for legal, accounting and consulting services during fiscal year 2004. As we continue to grow, expand 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.

*Other Operating Costs.* For fiscal year 2004, other operating costs were \$250,000. We had no corresponding operating costs for 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 litigation. Legal and related expenses increased to \$7.8 million in fiscal year 2004 from \$307,000 in fiscal year 2003. These costs are 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 year 2003. The decline in interest income is attributable to lower yields on securities investments. Gain from the sale of marketable securities was \$121,000 during fiscal year 2004 compared to \$114,000 in fiscal year 2003.

*Income Taxes.* The income tax benefit of \$11.2 million and \$3.9 million taken in fiscal year 2004 and 2003, respectively, primarily related to the release of the valuation allowance previously established for our net operating losses. We released \$10.2 million of valuation allowance in fiscal year 2004 and \$4.2 million in fiscal year 2003.

*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. During fiscal year 2003 the loss from discontinuing operations related to the operations of WellCheck through December 23, 2003 when the business was sold.

*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

32



**Table of Contents**

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.

**LIQUIDITY AND CAPITAL RESOURCES**

Cash flow information for the three years ended March 25, 2005 was as follows (in thousands):

	<b>Mar 25, 2005</b>	<b>Mar 26, 2004</b>
Cash, cash equivalents, and marketable securities	\$ 33,468	\$ 23,602
Net cash provided by (used in) operating activities	10,242	(1,124)
Net cash used in investing activities	(11,432)	(7,165)
Net cash provided by financing activities	2,992	2,044
Net increase (decrease) in cash and cash equivalents	\$ 1,802	\$ (6,245)

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 25, 2005, we have raised \$87.3 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 September 2004 and will expire in September 2006. 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. We did not borrow under this line of credit during fiscal year 2005. As a result, there were no limitations on our deposited assets.

*Cash Provided by (Used in) Operating Activities.* The net cash provided by operations increased \$11.4 million to \$10.2 million for fiscal year 2005. Net cash provided by operations was primarily attributable to net income of \$4.1 million and \$4.9 million of non-cash adjustments, including depreciation and deferred taxes. Accounts receivable decreased \$1.4 million due to a more consistent distribution of revenue within the fiscal year related to the end of quarter end discounts to distribution partners. This was offset by a \$2.2 million increase in inventory due to an anticipation of increased sales volumes.

The \$1.1 million use of cash in operations during fiscal year 2004 was primarily attributed 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. This was countered 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.

*Cash Used in Investing Activities.* Investing activities resulted in the net use of \$11.4 million of cash during fiscal year 2005. Spending on additional manufacturing equipment, facilities improvements and software accounted for \$3.1 million of capital improvements, as well as an \$8.3 million purchase of marketable securities during the year. During fiscal year 2006, we intend to invest approximately \$5.0 million in capital purchases related to expansion of our manufacturing capacity, research and development, computer systems and tenant improvements.

**Table of Contents**

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.

*Cash Provided by Financing Activities.* Cash provided by financing activities for fiscal years 2005, 2004 and 2003 relate to the issuance of common stock pursuant to the employee stock incentive and employee stock purchase plans. During fiscal years 2005 and 2004 we raised \$3.0 million and \$2.0 million, respectively, 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 25, 2005, and the effect such obligations are expected to have on our liquidity and cash flow in future periods is (in thousands):

	Payments Due by Period				
	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years	Total
Operating lease obligations(1)	\$ 1,074	\$ 2,271	\$ 1,883	\$ 3,567	\$ 8,795
Purchase obligations	999	219			1,218
<b>Total</b>	<b>\$ 2,073</b>	<b>\$ 2,490</b>	<b>\$ 1,883</b>	<b>\$ 3,567</b>	<b>\$ 10,013</b>

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

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 by operations for fiscal years 2000 through 2005, and we expect to continue to generate cash from operations for the foreseeable future.

In our efforts to grow, we are looking to acquire technologies which could complement our current product offering. However, should we acquire such technologies 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 financings 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**(In thousands, except share data)  
(unaudited)

	<b>Quarter Ended</b>							
	<b>Mar. 25, 2005</b>	<b>Dec. 24, 2004</b>	<b>Sept. 24, 2004</b>	<b>June 25, 2004</b>	<b>Mar. 26, 2004</b>	<b>Dec. 26, 2003</b>	<b>Sept. 26, 2003</b>	<b>June 27, 2003</b>
Revenue	\$ 15,214	\$ 14,573	\$ 13,537	\$ 9,553	\$ 11,942	\$ 13,363	\$ 13,357	\$ 13,714
Gross profit	9,323	8,802	7,813	5,549	6,090	7,197	7,740	8,169
Income (loss) from continuing operations	1,808	1,678	1,001	(346)	10,439	(3,951)	916	1,269
Gain (loss) from discontinued operations	2	1	4	1	5	5	9	15
Net income (loss)	\$ 1,810	\$ 1,679	\$ 1,005	\$ (345)	\$ 10,444	\$ (3,946)	\$ 925	\$ 1,284
Income (loss) from continuing operations per share								
Basic	\$ 0.13	\$ 0.12	\$ 0.07	\$ (0.02)	\$ 0.74	\$ (0.28)	\$ 0.07	\$ 0.09
Diluted	\$ 0.12	\$ 0.12	\$ 0.07	\$ (0.02)	\$ 0.73	\$ (0.28)	\$ 0.06	\$ 0.09
Loss from discontinued operations per share								
Basic	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00
Diluted	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00
Earnings (loss) per share:								
Basic	\$ 0.13	\$ 0.12	\$ 0.07	\$ (0.02)	\$ 0.74	\$ (0.28)	\$ 0.07	\$ 0.09
Diluted	\$ 0.12	\$ 0.12	\$ 0.07	\$ (0.02)	\$ 0.73	\$ (0.28)	\$ 0.06	\$ 0.09

**CRITICAL ACCOUNTING POLICIES**

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

35

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## **Table of Contents**

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 Doubtful Accounts*

We maintain an accounts receivable allowance for an estimated amount of losses that may result from a customer's inability to pay for products 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. The allowance for doubtful accounts was \$230,000 and \$169,000 for fiscal years 2005 and 2004, respectively.

### *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 in the provision for excess, obsolete and unusable inventory, which was \$419,000, \$651,000 and \$92,000 in fiscal years 2005, 2004 and 2003, 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 its 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 Statement on Financial Accounting Standards, 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 value used to determine the amount of compensation is based on several estimates including expected stock volatility, expected life of grant and expected employee turnover.

### **RECENT ACCOUNTING PRONOUNCEMENTS**

In November 2004, the Financial Accounting Standards Board, FASB , issued SFAS No. 151, *Inventory Costs*, an amendment of ARB No. 43, Chapter 4, ( SFAS 151 ). SFAS 151 clarifies that abnormal inventory costs such as costs of idle facilities, excess freight and handling costs, and wasted materials (spoilage) are required to be recognized as current period charges. The provisions of SFAS 151 are effective for the fiscal

## Table of Contents

year beginning after June 15, 2005. The adoption of SFAS 151 is not expected to have a material impact on our consolidated financial position, results of operations and cash flows.

In December 2004, the FASB issued SFAS No. 153, Exchanges of Non-monetary Assets, an amendment of APB Opinion No. 29, ( SFAS 153 ). SFAS 153 addresses the measurement of exchanges of non-monetary assets and redefines the scope of transactions that should be measured based on the fair value of the assets exchanged. SFAS 153 is effective for non-monetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. The adoption of SFAS 153 is not expected to have a material effect on the Company's consolidated financial position or results of operations.

In December 2004, the FASB issued SFAS No. 123 (revised 2004), Share-Based Payment, ( SFAS 123(R) ). SFAS 123(R) will require us to measure all employee stock-based compensation awards using a fair value method and record such expense in its consolidated financial statements. In addition, the adoption of SFAS 123(R) will require additional accounting related to the income tax effects and additional disclosure regarding the cash flow effects resulting from share-based payment arrangements. On March 23, 2005, our Board of Directors approved an acceleration of vesting for all outstanding unvested stock options with a per share exercise price equal to or greater than \$12.06. The primary purpose of the acceleration of vesting was to eliminate future compensation expense we would otherwise recognize in our income statement with respect to these accelerated options upon the adoption of SFAS 123(R). The aggregate estimated compensation expense associated with these accelerated options that would have been recognized in our income statements after adoption of SFAS 123(R), prior to the delay discussed below, was approximately \$1.1 million. As a result, options to purchase 93,337 shares of our common stock became immediately exercisable as of March 23, 2005. Of the total options accelerated, our executive officers held options to purchase an aggregate of 27,085 shares of common stock.

In March 2005, the Securities and Exchange Commission ( SEC ) issued Staff Accounting Bulletin No. 107 ( SAB 107 ) which provides guidance regarding the application of SFAS 123(R). SAB 107 expresses views of the staff regarding the interaction between SFAS No. 123(R) and certain SEC rules and regulations and provides the staff's views regarding the valuation of share-based payment arrangements for public companies. In particular, SAB 107 provides guidance related to share-based payment transactions with nonemployees, the transition from nonpublic to public entity status, valuation methods (including assumptions such as expected volatility and expected term), the accounting for certain redeemable financial instruments issued under share-based payment arrangements, the classification of compensation expense, non-GAAP financial measures, first-time adoption of SFAS 123(R) in an interim period, capitalization of compensation cost related to share-based payment arrangements, the accounting for income tax effects of share-based payment arrangements upon adoption of SFAS 123(R), the modification of employee share options prior to adoption of SFAS 123(R) and disclosures in Management's Discussion and Analysis ( MD&A ) subsequent to adoption of SFAS 123(R).

On April 14, 2005, the SEC approved a new rule that delays the effective date for SFAS 123(R) to annual periods beginning after June 15, 2005. The adoption of SFAS 123(R) on April 1, 2006 is expected to have a material impact on our results of operations, financial position and statement of cash flows. We are evaluating the transition method and pricing model alternatives upon adoption.

**Table of Contents**

**FACTORS AFFECTING FUTURE OPERATING RESULTS**

***We have a history of 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 25, 2005, we had an accumulated deficit of \$24.7 million. We recorded a net profit of \$4.9 million for fiscal year 2003, a net profit of \$8.7 million for fiscal year 2004, and a net profit of \$4.1 million for fiscal year 2005. 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;

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.





**Table of Contents**

***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 ten 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.

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. As a part of the settlement, we 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 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

**Table of Contents**

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 26, 2004 and March 25, 2005, the price of our common stock, as reported on the NASDAQ National Market System, has ranged from a low of \$6.16 to a high of \$13.68. 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.

## Table of Contents

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, 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.

**Table of Contents**

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

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

***We 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. 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

## Table of Contents

may harm our financial results due to unexpected 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 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, 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;
- 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

**Table of Contents**

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;

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

## Table of Contents

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 increased;

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

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

we manufacture all 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 newest 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.





**Table of Contents**

***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 newest 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 2005 and 14% in fiscal year 2004. We anticipate that international revenue will continue to represent a significant portion of our total revenue in the future. Our revenue is generally denominated in United States dollars; however, a strengthening of the dollar could make our products less competitive in foreign markets and, as a result, our future revenue from international operations may be unpredictable. We make foreign currency denominated purchases related to our GDX System in the United Kingdom. This exposes us to risks associated with currency exchange fluctuations. To minimize this risk, we have undertaken certain foreign currency hedging transactions; however, weakening of the dollar could make the cost of the GDX System less competitive in the domestic market, resulting in less predictable domestic revenue.

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

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

unexpected changes in regulatory requirements;

the impact of recessions in economies outside the United States;

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

less effective protection of intellectual property rights in some countries;

changes in tariffs and other trade protection measures;

difficulties in managing international operations; and

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

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

**Table of Contents**

***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 approximately 67% of our revenue in fiscal year 2005. In fiscal year 2005, Physicians Sales and Service accounted for approximately 24% of our total revenue, Henry Schein Inc. accounted for approximately 9% and McKesson Medical Surgical accounted for approximately 7% of our total revenue. In fiscal year 2004, Physicians Sales and Service accounted for approximately 23% of our total revenue, Henry Schein Inc. accounted for approximately 9% and McKesson Medical Surgical accounted for approximately 8% 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.

***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 correspond-

## Table of Contents

ing 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.

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 develop-

48

**Table of Contents**

ments 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.

***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

## Table of Contents

and understanding of our industry. We may be unable to retain our key personnel or attract or retain other necessary highly qualified personnel in the future, which would harm the development of our business.

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

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

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

50

**Table of Contents**

***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.

51

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**Table of Contents**

## 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 2007 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 use forward exchange contracts to manage a portion of the foreign currency exposures arising from inventory purchases and accounts payable denominated in foreign currencies. As of March 25, 2005, we had one outstanding forward contract to purchase £33,000 for approximately \$61,000. The open contract matures on April 15, 2005 and hedges certain forecasted inventory purchases denominated in the British Pound Sterling. There was no unrealized gain or loss on the forward contract as of March 25, 2005. There was no gain or loss recorded in the period from hedge ineffectiveness or from forecasted transactions no longer expected to occur. We do not enter into foreign exchange forward contracts for trading purposes.

We do not expect gains or losses on these contracts to have a material impact on our financial results.

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

	<b>Fiscal Year</b>				
	<b>2005</b>	<b>2006</b>	<b>2007</b>	<b>Total</b>	<b>Fair Value</b>
	<b>(in thousands)</b>				
Cash and cash equivalents	\$ 4,304	\$	\$	\$ 4,304	\$ 4,304
Short-term marketable securities	\$ 19,574	\$	\$	\$ 19,574	\$ 19,574
Weighted average interest rate	3.74%				
Long-term marketable securities	\$	\$ 494	\$ 9,096	\$ 9,590	\$ 9,590
Weighted average interest rate		2.80%	3.69%		

**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.

## Table of Contents

We have the ability to hold a significant 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 accountants' report appear on pages F-1 to F-26 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.* The Company's principal executive and financial officers evaluated the Company's disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) as of the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, the Company's principal executive and financial officers concluded that the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed in reports that we file or submit under the Exchange Act 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 were no changes in the Company's internal control over financial reporting during the quarter ended March 25, 2005 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

#### Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting for the Company. The Company's internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

To evaluate the effectiveness of internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act, management conducted an assessment, including testing, using the criteria in *Internal Control Integrated Framework*, issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on their assessment, management concluded the Company maintained effective internal control over financial reporting as of March 25, 2005, based on criteria in *Internal Control Integrated Framework* issued by the COSO. Management's assessment of the effectiveness of the Company's internal control over financial reporting as of March 25, 2005, has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in its report which is included herein.



## **Table of Contents**

### **Item 9B. Other Information**

None.

## **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 2005 Annual Meeting of Shareholders to be held August 17, 2005, 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** and **Corporate Governance** 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.

54

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## **Part IV**

### **Item 15. Exhibits and Financial Statement Schedules**

#### **(a)(1) Financial Statements.**

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

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	F-1
<u>Consolidated Balance Sheets at March 25, 2005 and March 26, 2004</u>	F-3
<u>Consolidated Statements of Operations for the years ended March 25, 2005, March 26, 2004 and March 28, 2003</u>	F-4
<u>Consolidated Statement of Changes in Shareholders' Equity for the years ended March 25, 2005, March 26, 2004 and March 28, 2003</u>	F-5
<u>Consolidated Statements of Cash Flows for the years ended March 25, 2005, March 26, 2004 and March 28, 2003</u>	F-6
<u>Notes to Consolidated Financial Statements</u>	F-7
<b>(a)(2) Financial Statement Schedules.</b>	
<u>Schedule II Valuation and Qualifying Accounts</u>	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)	Amended and Restated Preferred Share Rights Agreement dated January 1, 2005 between Registrant and Computershare Investor Services, LLC, 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
10.17.10(6)	Revolving Line of Credit Note effective September 1, 2004 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

**Table of Contents**

10.29(10)	2000 Stock Incentive Program, as amended, and form of agreement thereto
10.29.1	Form of 2000 Stock Incentive Program Notice of Grant of Stock Purchase Right
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
10.37.1(13)	Lease Agreement Addendum No. One by and between Registrant and BIV Group dated November 19, 2004
10.38(14)	2002 Employee Stock Purchase Plan and form of agreement thereto
10.39(15)	Stock Purchase Agreement dated December 23, 2002 between Registrant, WellCheck Inc. and ImpactHealth.com, Inc.
10.40(16)	Amended and Restated Severance Arrangement between Registrant and Warren E. Pinckert II dated June 14, 2001
10.40.1(16)	First Amendment to Amended and Restated Severance Arrangement between Registrant and Warren E. Pinckert II dated March 27, 2003
10.41(16)	Change of Control Severance Agreement between Registrant and Warren E. Pinckert II dated June 14, 2001
10.41.1(16)	First Amendment to Change of Control Severance Agreement between Registrant and Warren E. Pinckert II dated January 23, 2003
10.41.2(17)	Amended and Restated Change of Control Severance Agreement between Registrant and Warren E. Pinckert II dated March 25, 2004
10.42(16)	Severance Agreement between Registrant and William W. Burke dated July 17, 2001
10.43(16)	Change of Control Severance Agreement between Registrant and William W. Burke dated July 21, 2001
10.43.1(16)	First Amendment to Change of Control Severance Agreement between Registrant and William W. Burke dated January 23, 2003
10.43.2(17)	Amended and Restated Change of Control Severance Agreement between Registrant and William W. Burke dated March 25, 2004
10.46(16)	Severance Agreement between Registrant and Terry L. Wassmann dated July 17, 2001
10.46.1(16)	First Amendment to Severance Agreement between Registrant and Terry L. Wassmann dated January 23, 2003
10.47(16)	Change of Control Severance Agreement between Registrant and Terry L. Wassmann dated January 23, 2003
10.47.1(16)	First Amendment to Change of Control Severance Agreement between Registrant and Terry L. Wassmann dated January 23, 2003
10.47.2(17)	Amended and Restated Change of Control Severance Agreement between Registrant and Terry L. Wassmann dated March 25, 2004
10.48(16)	Severance Agreement between Registrant and Thomas E. Worthy dated July 19, 2001
10.48.1(18)	First Amendment to Severance Agreement between Registrant and Thomas E. Worthy dated October 10, 2003
10.50(16)	Employment Agreement between Registrant and Donald P. Wood dated March 31, 2003

**Table of Contents**

10.51(16)	Severance Agreement between Registrant and Donald P. Wood dated April 1, 2003
10.51.1(18)	First Amendment to Severance Agreement between Registrant and Donald P. Wood dated October 10, 2003
10.52(18)	Change of Control Severance Agreement between Registrant and Donald P. Wood dated October 10, 2003
10.52.1(17)	Amended and Restated Change of Control Severance Agreement between Registrant and Donald P. Wood dated March 25, 2004
10.54(18)	Change of Control Severance Agreement between Registrant and Thomas E. Worthy dated October 10, 2003
10.54.1(17)	Amended and Restated Change of Control Severance Agreement between Registrant and Thomas E. Worthy dated March 25, 2004
10.55(18)	Change of Control Severance Agreement between Registrant and Kenneth F. Miller dated June 2, 2004
10.56(19)	Severance Agreement between Registrant and John F. Glenn dated October 12, 2004
10.57(19)	Change of Control Severance Agreement between Registrant and John F. Glenn dated October 12, 2004
10.58(6)	Transition Agreement between Registrant and William W. Burke dated July 21, 2004
10.59(20)	Change of Control Severance Agreement dated February 1, 2005 between Registrant and Barbara McAleer
10.60(20)	Severance Agreement dated February 1, 2005 between Registrant and Barbara McAleer
23.1	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (see page 59)
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-K filed with the Securities and Exchange Commission on January 5, 2005.
- (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 September 24, 2004.
- (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.



**Table of Contents**

- (8) Incorporated by reference to exhibits filed with Registrant's Registration Statement on Form S-8 (333-94503) as declared effective by the Securities and Exchange Commission on January 12, 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 Report on Form 8-K filed with the Securities and Exchange Commission on November 23, 2004.
- (14) 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.
- (15) Incorporated by reference to exhibits filed with Registrant's Report on Form 8-K filed with the Securities and Exchange Commission on January 6, 2003.
- (16) Incorporated by reference to exhibits filed with Registrant's Annual Report on Form 10-K for the fiscal year ended March 28, 2003.
- (17) Incorporated by reference to exhibits filed with Registrant's Annual Report on Form 10-K for the fiscal year ended March 26, 2004.
- (18) Incorporated by reference to exhibit filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended December 26, 2003.
- (19) Incorporated by reference to exhibits filed with Registrant's Report on Form 8-K filed with the Securities and Exchange Commission on October 14, 2004.
- (20) Incorporated by reference to exhibits filed with Registrant's Report on Form 8-K filed with the Securities and Exchange Commission on February 2, 2005.
- (b) *Exhibits.*  
See Item 15(a)(3) above.
- (c) *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

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

Date: June 8, 2005

**Power of Attorney**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Warren E. Pinckert II and John F. Glenn, 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:

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ WARREN E. PINCKERT II  (Warren E. Pinckert II)	President, Chief Executive Officer and Director (Principal Executive Officer)	June 8, 2005
/s/ JOHN F. GLENN  (John F. Glenn)	Vice President of Finance, Chief Financial Officer, Treasurer and Secretary (Principal Financial and Accounting Officer)	June 8, 2005
/s/ JOHN H. LANDON  (John H. Landon)	Director	June 8, 2005
/s/ MICHAEL D. CASEY  (Michael D. Casey)	Director	June 8, 2005
/s/ JOHN L. CASTELLO  (John L. Castello)	Director	June 8, 2005
/s/ ELIZABETH H. DAVILA  (Elizabeth H. Davila)	Director	June 8, 2005

/s/ STUART HEAP	Director	June 8, 2005
(Stuart Heap)		
/s/ LARRY Y. WILSON	Director	June 8, 2005
(Larry Y. Wilson)		



**Table of Contents**

Report of Independent Registered Public Accounting Firm

To the Board of Directors and  
Shareholders of Cholestech Corporation:

We have completed an integrated audit of Cholestech Corporation's 2005 consolidated financial statements and of its internal control over financial reporting as of March 25, 2005 and audits of its March 26, 2004 and March 28, 2003 consolidated financial statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Our opinions, based on our audits, are presented below.

**Consolidated financial statements and financial statement schedule**

In our opinion, the consolidated 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 25, 2005 and March 26, 2004, and the results of its operations and its cash flows for each of the three years in the period ended March 25, 2005 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 consolidated financial statements. These financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit of financial statements 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.

**Internal control over financial reporting**

Also, in our opinion, management's assessment, included in Management's Report on Internal Control Over Financial Reporting appearing under Item 9A, that the Company maintained effective internal control over financial reporting as of March 25, 2005 based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), is fairly stated, in all material respects, based on those criteria. Furthermore, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of March 25, 2005, based on criteria established in Internal Control - Integrated Framework issued by the COSO. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express opinions on management's assessment and on the effectiveness of the Company's internal control over financial reporting based on our audit. We conducted our audit of internal control over financial reporting in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. An audit of internal control over financial reporting includes obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effective-

F-1

**Table of Contents**

ness of internal control, and performing such other procedures as we consider necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP

San Jose, California

June 7, 2005

F-2

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**Table of Contents**

Cholestech Corporation  
Consolidated Balance Sheets  
(In thousands, except share data)

	March 25, 2005	March 26, 2004
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 4,304	\$ 2,502
Marketable securities	19,574	11,300
Accounts receivable, net	4,651	6,038
Inventories, net	8,356	6,083
Prepaid expenses and other assets	1,889	1,715
Note receivable		200
Deferred tax assets	2,333	2,100
Total current assets	41,107	29,938
Property and equipment, net	8,176	8,257
Long-term marketable securities	9,590	9,800
Long-term deferred tax assets	15,248	15,235
Total assets	\$ 74,121	\$ 63,230
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 4,259	\$ 3,149
Accrued payroll and benefits	2,984	2,489
Other liabilities	286	314
Total current liabilities	7,529	5,952
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; 14,614,914 and 14,095,075 shares issued and outstanding at March 25, 2005 and March 26, 2004, respectively	91,681	86,009
Accumulated other comprehensive income (loss)	(116)	149
Deferred compensation	(241)	
Accumulated deficit	(24,732)	(28,880)
Total shareholders' equity	66,592	57,278
Total liabilities and shareholders' equity	\$ 74,121	\$ 63,230

See accompanying notes to consolidated financial statements.

F-3

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**Table of Contents**

Cholestech Corporation  
Consolidated Statements of Operations  
(In thousands, except per share data)

	<b>Fiscal Year Ended</b>		
	<b>March 25, 2005</b>	<b>March 26, 2004</b>	<b>March 28, 2003</b>
Revenue	\$ 52,877	\$ 52,376	\$ 48,541
Cost of revenue	21,390	23,180	20,424
Gross profit	31,487	29,196	28,117
Operating expenses:			
Sales and marketing	11,494	12,654	11,737
Research and development	4,252	3,159	2,722
General and administrative	9,864	8,153	7,008
Other operating costs		250	
Litigation and other related		7,786	307
Total operating expenses	25,610	32,002	21,774
Income (loss) from operations	5,877	(2,806)	6,343
Interest and other income, net	231	278	438
Income (loss) before taxes	6,108	(2,528)	6,781
Provision (benefit) for income taxes	1,968	(11,201)	(3,934)
Income from continuing operations	4,140	8,673	10,715
Loss from sale of discontinued operations, net			(4,445)
Gain (loss) from discontinued operations, net	8	34	(1,377)
Net income	\$ 4,148	\$ 8,707	\$ 4,893
Income from continuing operations per share:			
Basic	\$ 0.29	\$ 0.62	\$ 0.79
Diluted	\$ 0.29	\$ 0.61	\$ 0.76
Gain (loss) from discontinued operations per share:			
Basic	\$ 0.00	\$ 0.01	\$ (0.43)
Diluted	\$ 0.00	\$ 0.00	\$ (0.41)
Net income per share:			
Basic	\$ 0.29	\$ 0.63	\$ 0.36
Diluted	\$ 0.29	\$ 0.61	\$ 0.35

Shares used to compute net income (loss) per share:

Basic	14,295	13,922	13,551
Diluted	14,472	14,235	14,077

See accompanying notes to consolidated financial statements.

F-4

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**Table of Contents**

Cholestech Corporation  
Consolidated Statement of Changes in Shareholders' Equity  
(In thousands, except share data)

	<b>Common Stock</b>		<b>Accumulated Other Comprehensive Income (Loss)</b>	<b>Deferred Compensation</b>	<b>Accumulated Deficit</b>	<b>Total</b>
	<b>Shares</b>	<b>Amount</b>				
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 (loss) on available-for-sale securities, net			96			96
Change in future currency contracts, net			(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 (loss) on available-for-sale securities, net			(66)			(66)
Change in future currency contracts, net			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	\$ 86,009	\$ 149		\$ (28,880)	\$ 57,278
Net income					4,148	4,148

Change in unrealized gain (loss) on available-for-sale securities, net			(188)			(188)
Change in future currency contracts, net			(77)			(77)
Comprehensive income						3,883
Issuance of Common Stock pursuant to employee stock purchase plan and exercise of stock options	496,157	2,992				2,992
Issuance of restricted stock	23,682	241		(241)		
Tax benefit on non-qualified stock options		2,439				2,439
Balance at March 25, 2005	14,614,914	\$ 91,681	\$ (116)	\$ (241)	\$ (24,732)	\$ 66,592

See accompanying notes to consolidated financial statements.

F-5



Table of Contents

Cholestech Corporation  
Consolidated Statements of Cash Flows  
(In thousands)

	Fiscal Year Ended		
	March 25, 2005	March 26, 2004	March 28, 2003
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net income	\$ 4,148	\$ 8,707	\$ 4,893
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	3,184	2,709	2,553
Change in allowance for doubtful accounts	(61)	54	59
Change in inventory reserve	(395)	651	92
Change in allowance for sales returns		(5)	(20)
Deferred tax asset	2,193	(11,426)	(4,200)
Loss on sale of WellCheck			4,445
Stock acceleration charge			(72)
Changes in assets and liabilities:			
Accounts receivable	1,448	(892)	(1,509)
Inventories	(1,878)	72	(1,941)
Prepaid expenses and other assets	(174)	274	(845)
Notes receivable	200	50	
Accounts payable and accrued liabilities	1,110	(808)	461
Accrued payroll and benefits	495	(684)	(227)
Other liabilities	(28)	174	24
Net cash provided by (used in) operating activities	10,242	(1,124)	3,713
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchases of marketable securities	(31,560)	(47,894)	(49,427)
Maturities of marketable securities	23,231	44,204	45,472
Purchase of property and equipment	(3,103)	(3,475)	(2,925)
Net cash used in investing activities	(11,432)	(7,165)	(6,880)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Issuance of common stock	2,992	2,044	3,218
Purchase of authorized but unissued stock			(104)
Net cash provided by financing activities	2,992	2,044	3,114
Net increase (decrease) in cash and cash equivalents	1,802	(6,245)	(53)
Cash and cash equivalents at beginning of year	2,502	8,747	8,800

Cash and cash equivalents at end of year	\$	4,304	\$	2,502	\$	8,747
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**Supplemental disclosures of cash flow  
information and non-cash transactions:**

Cash paid for income taxes	\$	148	\$	590	\$	59
Cash paid for legal settlement			\$	7,000		
Tax benefits of nonqualified stock options	\$	2,439	\$	1,723		
Issuance of restricted stock	\$	241				

See accompanying notes to consolidated financial statements.

F-6

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**Table of Contents**

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. 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. The quantitative measure of A1C is established as an indicator of a patient's long-term glycemic control. 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 2005, 2004 and 2003 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 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. 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. Our general terms of sale are FOB shipping point and revenue recognition at time of shipment. When the terms of sale are FOB receiving point, assuming that all other revenue recognition criteria have been met, revenue is recognized when the products have reached the destination point.

The Company offers an early payment discount to qualified 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

F-7

**Table of Contents**

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***

The Company considers all highly liquid investments with maturities of three months or less at the date of purchase to be cash equivalents. Cash equivalents as of March 25, 2005 consist principally of investments in money market funds.

***Marketable securities***

Marketable securities and 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. Marketable securities as of March 25, 2005 consist principally of investments in commercial paper, corporate bonds 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.

The cost and fair market value of available-for-sale securities as of March 25, 2005 are as follows (in thousands):

	<b>Amortized Cost</b>	<b>Unrealized Gain (Loss)</b>	<b>Fair Market Value</b>	<b>Maturity Date</b>
<b>Short-term marketable securities</b>				
Commercial paper	\$ 2,126	\$ (6)	\$ 2,120	May 2005 - March 2006
Corporate bonds	5,880	(38)	5,842	April 2005 - February 2006
Government agency	11,685	(73)	11,612	May 2005 - March 2006
	<b>\$ 19,691</b>	<b>\$ (117)</b>	<b>\$ 19,574</b>	
<b>Long-term marketable securities</b>				
Commercial paper	\$ 500	\$ (4)	\$ 496	April 2006
Corporate bonds	3,144	(34)	3,110	March 2006 - December 2006
Government agency	6,058	(74)	5,984	April 2006 - January 2007
	<b>\$ 9,702</b>	<b>\$ (112)</b>	<b>\$ 9,590</b>	

F-8

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**Table of Contents**

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

	<b>Amortized Cost</b>	<b>Unrealized Gain (Loss)</b>	<b>Fair Market Value</b>	<b>Maturity Date</b>
<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
	<b>\$ 11,292</b>	<b>\$ 8</b>	<b>\$ 11,300</b>	
<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
	<b>\$ 9,778</b>	<b>\$ 22</b>	<b>\$ 9,800</b>	

There was \$229,000 in unrealized losses as of March 25, 2005 included in accumulated other comprehensive income in shareholders' equity and \$30,000 in unrealized gains as of March 26, 2004.

***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 25, 2005, the Company had outstanding one forward contract to purchase £33,000 for approximately \$61,000. The open contract matures on April 15, 2005 and hedges certain forecasted inventory purchases denominated in the British Pound Sterling. There was no unrealized gain or loss on

the forward contract as of March 25, 2005. There was no gain or loss recorded during the year 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

F-9

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**Table of Contents**

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.

Concentration of credit risk with respect to trade accounts receivable is considered to be limited due to the quality of our 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.

Significant revenue concentration (in thousands):

	March 25, 2005		March 26, 2004		March 28, 2003	
	Revenue	Percent of Total	Revenue	Percent of Total	Revenue	Percent of Total
Customer A	\$ 12,467	24%	\$ 11,967	23%	\$ 10,909	22%
Customer B	4,826	9	4,906	9	4,461	9
Customer C	3,695	7	4,073	8	3,401	7
Total	\$ 20,988	40%	\$ 20,946	41%	\$ 18,771	38%

Significant accounts receivable concentrations (in thousands):

	March 25, 2005		March 26, 2004	
	Receivable Balance	Percent of Total	Receivable Balance	Percent of Total
Customer A	\$ 744	16%	\$ 994	16%
Customer B	287	6	812	13
Customer C	385	8	851	14
Total	\$ 1,416	30%	\$ 2,657	43%

***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

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**Table of Contents**

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.

*Research and development*

Research and development costs are expensed as incurred. Research and development costs consist primarily of payroll and related costs, materials and supplies used in development of new products, and fees paid to consultants and outside service providers.

*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 shelf-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 years ended March 25, 2005 and March 26, 2004 were as follows:

<b>Fiscal Year Ended</b>	<b>March 25, 2005</b>	<b>March 26, 2004</b>
Balance at the beginning of the year	\$ 314,000	\$ 116,000
Accruals and charges for warranty for the year	779,000	970,000
Cost of repairs and replacements	(807,000)	(772,000)
Balance at the end of the year	\$ 286,000	\$ 314,000

*Advertising costs*

The cost of advertising is expensed as incurred. Advertising expenses were \$42,000, \$281,000, and \$175,000 for fiscal years 2005, 2004 and 2003, 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 year 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 net operating losses (NOLs). Net income in fiscal year 2003 included a \$4.2 million gain from the reversal of a portion of the valuation allowance. Prior to fiscal year 2003, the Company had experienced significant operating losses and operated in an industry subject to rapid technological change. Therefore, the Company believed that

F-11

**Table of Contents**

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 25, 2005	March 26, 2004	March 28, 2003
(In thousands, except per share data)			
<b>Income</b>			
Income from continuing operations	\$ 4,140	\$ 8,673	\$ 10,715
Income (loss) from discontinued operations	8	34	(5,822)
Net income	\$ 4,148	\$ 8,707	\$ 4,893
<b>Shares</b>			
Basic	14,295	13,922	13,551
Effect of dilutive securities	177	313	526
Diluted	14,472	14,235	14,077
<b>Per share continuing operations:</b>			
Basic	\$ 0.29	\$ 0.62	\$ 0.79
Effect of dilutive securities	(0.00)	(0.01)	(0.03)
Diluted	\$ 0.29	\$ 0.61	\$ 0.76
<b>Per share discontinued operations:</b>			
Basic	\$ 0.00	\$ 0.01	\$ (0.43)
Effect of dilutive securities	(0.00)	(0.01)	0.02
Diluted	\$ 0.00	\$ 0.00	\$ (0.41)
<b>Per share net income:</b>			
Basic	\$ 0.29	\$ 0.63	\$ 0.36
Effect of dilutive securities	(0.00)	(0.02)	(0.01)
Diluted	\$ 0.29	\$ 0.61	\$ 0.35

Options to purchase 380,407, 1,410,172 and 1,811,253 shares of common stock were considered anti-dilutive because the respective exercise prices were greater than the average fair market value of common stock as of March 25, 2005, March 26, 2004 and March 28, 2003, respectively.

*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.

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**Table of Contents***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 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 and restricted stock, 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 determined based on the fair 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:

	<b>Fiscal Year Ended</b>		
	<b>March 25, 2005</b>	<b>March 26, 2004</b>	<b>March 28, 2003</b>
	(In thousands, except per share data)		
Net income as reported	\$ 4,148	\$ 8,707	\$ 4,893
Deduct: total stock-based employee compensation expense determined under fair value based method for all awards, net of tax	(4,245)	(3,031)	(2,636)
Net income pro forma	\$ (97)	\$ 5,676	\$ 2,257
Net income per share:			
As reported basic	\$ 0.29	\$ 0.63	\$ 0.36
Pro forma basic	\$ (0.01)	\$ 0.41	\$ 0.17
As reported diluted	\$ 0.29	\$ 0.61	\$ 0.35
Pro forma diluted	\$ (0.01)	\$ 0.40	\$ 0.16

The pro forma information presented above for fiscal year 2005 includes approximately \$1.1 million of stock-based employee compensation related to the accelerated vesting of certain options in March 2005. The pro forma information for fiscal years 2004 and 2003 has been revised from the information previously presented in the Company's Form 10-K for the period ended March 26, 2004. Such pro forma disclosure may not be representative of future compensation costs as options vest over several years and additional grants are anticipated to be made each year.

F-13



**Table of Contents**

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

	<b>Fiscal Year Ended</b>		
	<b>March 25, 2005</b>	<b>March 26, 2004</b>	<b>March 28, 2003</b>
<b>Stock options:</b>			
Expected volatility	71.0%	85.0%	95.0%
Risk free interest rate	3.0%	1.0%	1.5%
Dividend yield	0.0%	0.0%	0.0%
Fair value of stock options granted	\$ 5.54	\$ 6.53	\$ 8.33
Expected Life	5.5 Years	7 Years	7 Years
<b>Stock purchase rights:</b>			
Expected volatility	74.0%	85.0%	69.0%
Dividend yield	0.0%	0.0%	0.0%
Fair value of stock purchase rights	\$ 1.14	\$ 1.36	\$ 1.72
Weighted Average exercise price	\$ 5.43	\$ 5.38	\$ 6.46
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 income and the related cost measured by the fair value method is presented above.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of SFAS 123 and 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 2005, fiscal year 2004 and fiscal year 2003.

***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 November 2004, the FASB issued SFAS No. 151, *Inventory Costs*, an amendment of ARB No. 43, Chapter 4, ( SFAS 151 ). SFAS 151 clarifies that abnormal inventory costs such as costs of idle facilities, excess freight and handling costs, and wasted materials (spoilage) are required to be recognized as current period charges. The provisions of SFAS 151 are effective for the fiscal year beginning after June 15, 2005. The adoption of SFAS 151 is not expected to have a material impact on the Company's consolidated financial position, results of operations and cash flows.

In December 2004, the FASB issued SFAS No. 153, *Exchanges of Non-monetary Assets*, an amendment of APB Opinion No. 29, ( SFAS 153 ). SFAS 153 addresses the measurement of exchanges of non-monetary assets and redefines the scope of transactions that should be measured based on the fair value of the





## Table of Contents

assets exchanged. SFAS 153 is effective for non-monetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. The adoption of SFAS 153 is not expected to have a material effect on the Company's consolidated financial position or results of operations.

In December 2004, the Financial Accounting Standards Board, FASB, issued SFAS No. 123 (revised 2004), Share-Based Payment, (SFAS 123(R)). SFAS 123(R) will require the Company to measure all employee stock-based compensation awards using a fair value method and record such expense in its consolidated financial statements. In addition, the adoption of SFAS 123(R) will require additional accounting related to the income tax effects and additional disclosure regarding the cash flow effects resulting from share-based payment arrangements.

In March 2005, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin No. 107 (SAB 107) which provides guidance regarding the application of SFAS 123(R). SAB 107 expresses views of the staff regarding the interaction between SFAS No. 123(R), Share-Based Payment, and certain SEC rules and regulations and provides the staff's views regarding the valuation of share-based payment arrangements for public companies. In particular, SAB 107 provides guidance related to share-based payment transactions with nonemployees, the transition from nonpublic to public entity status, valuation methods (including assumptions such as expected volatility and expected term), the accounting for certain redeemable financial instruments issued under share-based payment arrangements, the classification of compensation expense, non-GAAP financial measures, first-time adoption of SFAS 123(R) in an interim period, capitalization of compensation cost related to share-based payment arrangements, the accounting for income tax effects of share-based payment arrangements upon adoption of SFAS 123(R), the modification of employee share options prior to adoption of SFAS 123(R) and disclosures in Management's Discussion and Analysis (MD&A) subsequent to adoption of SFAS 123(R).

On April 14, 2005, the SEC approved a new rule that delays the effective date for SFAS 123(R) to annual periods beginning after June 15, 2005. The adoption of SFAS 123(R) on April 1, 2006 is expected to have a material impact on the Company's results of operations, financial position and statement of cash flows. The Company is evaluating the transition method and pricing model alternatives upon adoption.

## 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 year 2004 the terms of payment on the note receivable was changed to a quarterly payment of \$50,000. 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.

F-15

**Table of Contents**

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

	<b>March 25, 2005</b>	<b>March 26, 2004</b>	<b>March 28, 2003</b>
Revenue	\$	\$	\$ 1,472
Income (loss) before provision for income taxes	12	56	(1,489)
Income tax benefit (cost)	(4)	(22)	112
Net gain (loss)	\$ 8	\$ 34	\$ (1,377)

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 year 2003. The components of the loss are as follows (in thousands):

	<b>March 28, 2003</b>
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)
Net loss	\$ 4,445

### 3. Balance Sheet Composition

Accounts receivable consist of (in thousands), net:

	<b>March 25, 2005</b>	<b>March 26, 2004</b>
Accounts receivable	\$ 4,820	\$ 6,268
Less allowance for sales returns		
Less allowance for doubtful accounts	(169)	(230)
	\$ 4,651	\$ 6,038

Inventories consist of (in thousands), net:

	<b>March 25, 2005</b>	<b>March 26, 2004</b>
Raw materials	\$ 2,277	\$ 1,954
Work-in-progress	2,395	1,767
Finished goods	3,684	2,362

\$ 8,356 \$ 6,083

F-16

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**Table of Contents**

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

	March 25, 2005	March 26, 2004
Machinery and equipment	\$ 14,890	\$ 14,514
Furniture and fixtures	509	471
Computer equipment	3,330	2,766
Leasehold improvements	3,419	2,850
Patents	111	111
Construction-in-progress	632	566
	22,891	21,278
Less accumulated depreciation and amortization	(14,715)	(13,021)
	\$ 8,176	\$ 8,257

Depreciation and amortization expense of \$3.2 million, \$2.7 million and \$2.6 million was incurred in fiscal years 2005, 2004, and 2003, respectively.

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

	March 25, 2005	March 26, 2004
Trade accounts payable	\$ 2,492	\$ 1,466
Accrued accounting and reporting	596	405
Accrued royalties	855	666
Accrued legal expenses	105	172
Accrued rent	72	186
Other accrued liabilities	139	254
	\$ 4,259	\$ 3,149

#### 4. Borrowing Arrangements

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 in September 2006. As of March 25, 2005 and March 26, 2004, 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 a non-cancelable operating lease. The lease for the Company's headquarters facility was renewed during fiscal year 2005 and currently expires in March 2017. Rent expense was \$1.1 million, \$1.2 million and \$1.3 million for fiscal years 2005, 2004 and 2003, respectively.

F-17



**Table of Contents**

Future minimum payments required under the Company's non-cancelable operating lease as of March 25, 2005, were (in thousands):

2006	\$ 1,074
2007	1,115
2008	570
2009	586
2010	611
Thereafter	4,839
	<b>\$ 8,795</b>

*Litigation*

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 for each LDX Analyzer sold, a penalty of 1,000 for each cassette sold contrary to the prohibition and a 25,000 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 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. On March 24, 2004, the Constitutional Court issued its judgment which supported our claims. A hearing was scheduled for November 9, 2004 by the Judge of Seizures of the Court of First Instance to hear additional submissions. On December 21, 2004, the Judge of Seizures of the Court of First Instance decided against Euromedix's opposition to certain procedural issues. After the decisions of the Judge of Seizures of the Court of First Instance, we have filed requests for a procedural calendar in the three trademark infringement proceedings against Euromedix of which two are

F-18

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## Table of Contents

pending before the President of the Commercial Court of Leuven and one before the Commercial Court of Leuven. Both parties have exchanged submissions. All three cases are scheduled for pleadings at a hearing on June 21, 2005.

Euromedix has filed a request for a procedural calendar in the case pending before the Commercial Court of Leuven regarding the termination of the business relationship on July 11, 2002. We have to file submissions by August 18, 2005 and final submissions by October 3, 2005. The case is set for pleadings at the hearing of November 8, 2005.

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 alleged 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 sought 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 us. On January 18, 2005 the parties entered into an agreement to settle all claims on behalf of a nationwide class. Under the terms of the settlement, we paid \$625,000 in cash to settle all claims, \$600,000 of which was funded by insurance. We also agreed to pay up to \$50,000 for providing notice to the class and for processing claims. The Court granted preliminary settlement approval and a final settlement approval hearing is currently scheduled for July 11, 2005.

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.

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.

## 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

F-19

**Table of Contents**

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 of accrued payroll and benefits. The Company made payments of \$344,000 and \$178,000 to employees terminated under the fiscal year 2003 restructuring plan in fiscal year 2005 and fiscal year 2004, respectively. As of March 25, 2005, the Company does not expect to make any additional payments 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 25, 2005, nor was there any activity relating to preferred stock during the three year period ended March 25, 2005.

### *Stock incentive program*

In 1997, 1999 and 2000 the shareholders approved Stock Incentive Programs for the issuance of incentive stock options (ISOs) and non-qualified stock options (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	At least 25%	At least 25%	At least 25%
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 25, 2005	75,056	110,870	744,572



**Table of Contents**

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

	<b>Outstanding Options</b>	<b>Weighted Average Exercise Price Per Share</b>
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
Granted	633,400	9.00
Exercised	(401,200)	6.17
Canceled	(468,829)	10.49
Balance, March 25, 2005	2,124,035	9.75

The following table summarizes information about stock options outstanding as of March 25, 2005:

<b>Range of Exercise Prices</b>	<b>Options Outstanding</b>			<b>Options Exercisable</b>	
	<b>Number</b>	<b>Weighted Avg. Contractual Life(1)</b>	<b>Weighted Avg. Exercise Price</b>	<b>Number</b>	<b>Weighted Avg. Exercise Price</b>
\$4.28 - \$6.97	124,921	8.2	\$ 6.49	42,669	\$ 5.61
\$7.32 - \$8.29	758,858	7.1	7.78	519,798	7.75
\$8.30 - \$10.20	859,849	9.2	9.30	199,597	8.91
\$11.88 - \$17.85	380,407	7.1	15.76	287,080	15.69
	2,124,035	8.0	9.75	1,049,144	10.05

(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 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 95,038 and 85,521 shares of common stock to employees in fiscal year 2005 and fiscal year 2004, respectively.

F-21

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## **Table of Contents**

### *Restricted stock*

The Company grants restricted stock to key employees, under its 2000 Stock Incentive Program, as a means of retaining and rewarding them for long-term performance and to increase their ownership in the Company. Shares awarded under the plan entitle the shareholder to all rights of common stock ownership except that the shares may not be sold, transferred, pledged, exchanged or otherwise disposed of during the restriction period. The restriction period is determined by a committee, appointed by the board of directors, and may not exceed ten years.

The Company accounts for its restricted stock under APB Opinion No. 25, *Accounting for Stock Issued to Employees*. On March 23, 2005, 23,682 shares were granted with restriction periods of four years at a market price of \$10.19. The shares were recorded at the market value on the date of issuance as deferred compensation and the related amount is being amortized to operations over the respective vesting period. During the year ended March 25, 2005, unearned compensation charged to operations related to these shares of restricted stock was zero. At March 25, 2005, the weighted-average grant date fair value and weighted-average contractual life for outstanding shares of restricted stock was \$10.19 and four years, 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 option acceleration*

On March 23, 2005, the Board of Directors (the *Board*) of the Company, acting upon the recommendation of the Compensation Committee of the Board, approved an acceleration of vesting for all outstanding unvested stock options with a per share exercise price equal to or greater than \$12.06 (the *Acceleration*). These options had exercise prices in excess of the current market value of the common stock on March 23, 2005, therefore, no expense was recognized on the Acceleration. The options to purchase 93,337 shares of the Company's common stock at exercise prices ranging from \$12.06 to \$17.85 became immediately exercisable as of March 23, 2005.

During fiscal year 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 year 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.

F-22

**Table of Contents***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**

All employees of the Company can participate in the Cholestech Corporation Retirement Savings Plan ( the 401(k) Plan ) in which an 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. Employee contributions are fully vested and non-forfeitable at all times. The 401(k) Plan provides for discretionary employer contributions as determined by the board of directors. Company contributions to the 401(k) Plan were \$286,500, \$209,000 and \$0 in fiscal years 2005, 2004 and 2003, respectively.

**9. Income Taxes**

The provision (benefit) for income taxes from continuing operations consisted of (in thousands):

	<b>Federal</b>	<b>State</b>	<b>Total</b>
<b>Year ended March 25, 2005:</b>			
Current	\$ 2,091	\$ 70	\$ 2,161
Deferred	207	(400)	(193)
<b>Total</b>	<b>\$ 2,298</b>	<b>\$ (330)</b>	<b>\$ 1,968</b>
<b>Year ended March 26, 2004:</b>			
Current	\$	\$ 225	\$ 225
Deferred	(10,217)	(1,209)	(11,426)
<b>Total</b>	<b>\$ (10,217)</b>	<b>\$ (984)</b>	<b>\$ (11,201)</b>
<b>Year ended March 28, 2003:</b>			
Current	\$ 266	\$	\$ 266
Deferred	(4,200)		(4,200)
<b>Total</b>	<b>\$ (3,934)</b>	<b>\$</b>	<b>\$ (3,934)</b>

The differences between the expected federal statutory income tax rate of 34% and the Company's actual effective tax rate (or benefit) for fiscal years 2005, 2004 and 2003 are as follows:

	<b>Fiscal Year Ended</b>		
	<b>March 25, 2005</b>	<b>March 26, 2004</b>	<b>March 28, 2003</b>
Expected provision (benefit) at statutory rate	34.0%	(34.0)%	34.0%
State taxes, net of federal benefit	(3.6)	(25.7)	
Permanent differences	.5	1.9	2.5
Research and development credits	(.3)	(1.5)	(0.5)
Change in valuation allowance		(406.3)	(65.9)

Alternative minimum tax			1.7
Other	1.6	(74.0)	(29.7)
	32.2%	(539.6)%	(57.9)%

F-23

**Table of Contents**

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

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 25, 2005	March 26, 2004
Deferred tax assets:		
Net operating loss carryforwards	\$ 14,627	\$ 14,570
Accrued expenses	370	362
Inventory	319	473
Capitalized research and development	147	606
Research and development and other tax credits	1,878	1,560
Property and equipment	174	
Other	66	
<b>Total gross deferred tax assets</b>	<b>17,581</b>	<b>17,571</b>
Valuation allowance		
<b>Net deferred tax assets</b>	<b>17,581</b>	<b>17,571</b>
Deferred tax liabilities:		
Property and equipment		(236)
<b>Net deferred tax assets</b>	<b>\$ 17,581</b>	<b>\$ 17,335</b>

Management has assessed the need for a valuation allowance against deferred tax assets. Management believes it is more likely than not that the Company's deferred tax assets will be fully realized. Therefore, no valuation allowance has been established. The realizability of the deferred tax assets is primarily dependent on the ability of the Company to generate taxable income in the future. Subsequent changes in 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 25, 2005, the Company had net operating loss carryforwards of approximately \$42.6 million for federal tax purposes and \$2.7 million for state tax purposes, which will expire from 2006 through 2024, if not utilized. Additionally, the Company has federal and state tax credits, primarily research and development credits, of \$1.2 million for federal tax purposes and \$1.1 million for state tax purposes. The federal credits will expire from 2006 through 2024, if not utilized. Approximately \$438,000 of the state credits will expire from 2009 through 2013, if not utilized. In addition, \$654,000 of the state credits carryforward indefinitely.

Ownership changes, as defined under Section 382 of the Internal Revenue Code, have occurred. As a result, the annual limitation on utilization of net operating losses generated prior to December 16, 1992 is approximately \$5.7 million. The Company expects that this annual limitation will not cause any of the net operating losses to expire prior to utilization.



**Table of Contents**

9. 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.

10. 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 \$7.3 million, \$7.4 million and \$6.6 million in fiscal years 2005, 2004 and 2003, respectively. Sales to Europe were \$4.3 million, \$4.1 million and \$4.4 million in fiscal years 2005, 2004 and 2003, respectively, with the remainder of export sales to Asia and Latin America. All of the Company's assets are located in the United States.

F-25

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Table of Contents

Schedule II  
Cholestech Corporation  
Valuation and Qualifying Accounts

	Balance at Beginning of Period	Additions to Costs & Expenses	Deductions	Balance at End of Period
<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	\$ 54,000		\$ 230,000
Allowance for sales returns	5,000	(5,000)		
Inventory reserve	173,000	651,000		824,000
<b>Fiscal Year Ended March 25, 2005</b>				
Allowance for doubtful accounts	\$ 230,000	\$ 29,000	\$ 90,000	\$ 169,000
Inventory reserve	824,000		395,000	429,000

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

F-26

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**Table of Contents**

Exhibit Index

3.1(1)	Restated Articles of Incorporation of Registrant
3.2(2)	Bylaws of Registrant, as amended to date
4.2(3)	Amended and Restated Preferred Share Rights Agreement dated January 1, 2005 between Registrant and Computershare Investor Services, LLC, 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
10.17.10(6)	Revolving Line of Credit Note effective September 1, 2004 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
10.29.1	Form of 2000 Stock Incentive Program Notice of Grant of Stock Purchase Right
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
10.37.1(13)	Lease Agreement Addendum No. One by and between Registrant and BIV Group dated November 19, 2004
10.38(14)	2002 Employee Stock Purchase Plan and form of agreement thereto
10.39(15)	Stock Purchase Agreement dated December 23, 2002 between Registrant, WellCheck Inc. and ImpactHealth.com, Inc.
10.40(16)	Amended and Restated Severance Arrangement between Registrant and Warren E. Pinckert II dated June 14, 2001
10.40.1(16)	First Amendment to Amended and Restated Severance Arrangement between Registrant and Warren E. Pinckert II dated March 27, 2003
10.41(16)	Change of Control Severance Agreement between Registrant and Warren E. Pinckert II dated June 14, 2001
10.41.1(16)	First Amendment to Change of Control Severance Agreement between Registrant and Warren E. Pinckert II dated January 23, 2003
10.41.2(17)	Amended and Restated Change of Control Severance Agreement between Registrant and Warren E. Pinckert II dated March 25, 2004

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**Table of Contents**

10.42(16)	Severance Agreement between Registrant and William W. Burke dated July 17, 2001
10.43(16)	Change of Control Severance Agreement between Registrant and William W. Burke dated July 21, 2001
10.43.1(16)	First Amendment to Change of Control Severance Agreement between Registrant and William W. Burke dated January 23, 2003
10.43.2(17)	Amended and Restated Change of Control Severance Agreement between Registrant and William W. Burke dated March 25, 2004
10.46(16)	Severance Agreement between Registrant and Terry L. Wassmann dated July 17, 2001
10.46.1(16)	First Amendment to Severance Agreement between Registrant and Terry L. Wassmann dated January 23, 2003
10.47(16)	Change of Control Severance Agreement between Registrant and Terry L. Wassmann dated January 23, 2003
10.47.1(16)	First Amendment to Change of Control Severance Agreement between Registrant and Terry L. Wassmann dated January 23, 2003
10.47.2(17)	Amended and Restated Change of Control Severance Agreement between Registrant and Terry L. Wassmann dated March 25, 2004
10.48(16)	Severance Agreement between Registrant and Thomas E. Worthy dated July 19, 2001
10.48.1(18)	First Amendment to Severance Agreement between Registrant and Thomas E. Worthy dated October 10, 2003
10.50(16)	Employment Agreement between Registrant and Donald P. Wood dated March 31, 2003
10.51(16)	Severance Agreement between Registrant and Donald P. Wood dated April 1, 2003
10.51.1(18)	First Amendment to Severance Agreement between Registrant and Donald P. Wood dated October 10, 2003
10.52(18)	Change of Control Severance Agreement between Registrant and Donald P. Wood dated October 10, 2003
10.52.1(17)	Amended and Restated Change of Control Severance Agreement between Registrant and Donald P. Wood dated March 25, 2004
10.54(18)	Change of Control Severance Agreement between Registrant and Thomas E. Worthy dated October 10, 2003
10.54.1(17)	Amended and Restated Change of Control Severance Agreement between Registrant and Thomas E. Worthy dated March 25, 2004
10.55(18)	Change of Control Severance Agreement between Registrant and Kenneth F. Miller dated June 2, 2004
10.56(19)	Severance Agreement between Registrant and John F. Glenn dated October 12, 2004
10.57(19)	Change of Control Severance Agreement between Registrant and John F. Glenn dated October 12, 2004
10.58(6)	Transition Agreement between Registrant and William W. Burke dated July 21, 2004
10.59(20)	Change of Control Severance Agreement dated February 1, 2005 between Registrant and Barbara McAleer

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**Table of Contents**

10.60(20)	Severance Agreement dated February 1, 2005 between Registrant and Barbara McAleer
23.1	Consent of Independent Registered Public Accounting Firm
24.1	Power of Attorney (see page 59)
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-K filed with the Securities and Exchange Commission on January 5, 2005.
- (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 September 24, 2004.
- (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 (333-94503) as declared effective by the Securities and Exchange Commission on January 12, 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 Report on Form 8-K filed with the Securities and Exchange Commission on November 23, 2004.
- (14) 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.
- (15) Incorporated by reference to exhibits filed with Registrant's Report on Form 8-K filed with the Securities and Exchange Commission on January 6, 2003.
- (16) Incorporated by reference to exhibits filed with Registrant's Annual Report on Form 10-K for the fiscal year ended March 28, 2003.
- (17) Incorporated by reference to exhibits filed with Registrant's Annual Report on Form 10-K for the fiscal year ended March 26, 2004.
- (18) Incorporated by reference to exhibit filed with Registrant's Quarterly Report on Form 10-Q for the quarter ended December 26, 2003.

(19) Incorporated by reference to exhibits filed with Registrant's Report on Form 8-K filed with the Securities and Exchange Commission on October 14, 2004.

(20) Incorporated by reference to exhibits filed with Registrant's Report on Form 8-K filed with the Securities and Exchange Commission on February 2, 2005.