CHOLESTECH CORPORATION
Form 10-K
June 08, 2004

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United States
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

þ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDED MARCH 26, 2004

OR

o 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	**94-3065493**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
3347 Investment Boulevard Hayward, California	**94545**
(Address of principal executive offices)	(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 þ No o

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. þ

Indicate by check mark whether the registrant is an accelerated filer

(as defined in Rule 12b-2 of the Exchange Act). Yes þ No o

The aggregate market value of the voting stock held by non-affiliates of the registrant, based on the closing sale price of the common stock on September 26, 2003 as reported on the NASDAQ National Market, was approximately $80,034,000. Shares of common stock held by each executive officer and director and by each person who owns 5% or more of the outstanding common stock have been excluded from this computation. This determination of affiliate status is not necessarily a conclusive determination for other purposes. The registrant does not have any non-voting stock.

As of May 28, 2004, the registrant had outstanding 14,184,571 shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant has incorporated by reference into Part III of this Annual Report on Form 10-K portions of its Proxy Statement for the 2004 Annual Meeting of Shareholders to be held August 18, 2004.

CHOLESTECH CORPORATION

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

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PART I

Some of the statements contained in this Annual Report on Form 10-K are forward-looking statements about Cholestech Corporation (we, us or Cholestech), including but not limited to those specifically identified as such, that involve risks and uncertainties. The statements contained in the Report on Form 10-K that are not purely historical are forward looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, including, without limitation, statements regarding our expectations, beliefs, intentions or strategies regarding the future. All forward-looking statements included in this Report on Form 10-K are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors, which may cause our actual results to differ materially from those implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as may, will, should, expects, plans, anticipates, believes, estimates, predicts, potential or continue or the negative of these terms or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Moreover, neither any other person nor we assume responsibility for the accuracy and completeness of such statements. Important factors that may cause actual results to differ from expectations include those discussed in Factors Affecting Future Operating Results beginning on page 43 in this document.

We were incorporated under the laws of the State of California in February 1988. Our principal executive offices are located at 3347 Investment Boulevard, Hayward California 94545 and our telephone number at that location is (510) 732-7200.

ITEM 1. BUSINESS

Overview

We are a leading provider of diagnostic tools and information for immediate risk assessment and therapeutic monitoring of heart disease and diabetes. We currently manufacture the LDX® System (the LDX System), which includes the LDX Analyzer and a variety of single-use test cassettes and market the LDX System in the United States, Europe, Asia, Australia and South America. The LDX System, which is waived under the Clinical Laboratory Improvement Amendments (CLIA), allows healthcare providers to perform individual tests or combinations of tests with a single drop of blood from a fingerstick within five minutes. Our current products measure and monitor blood cholesterol, related lipids, glucose and liver function, and are used to test patients at risk of or suffering from heart disease, diabetes and liver disease. The LDX System can also provide the Framingham Risk Assessment from the patient s results as measured on the lipid profile cassette. In fiscal year 2004, revenue from sales of the LDX Analyzer and single use test cassettes represented over 90% of our revenue.

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

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The current healthcare system in the United States, while historically successful in treating acute conditions, is currently not adequately serving the growing need for preventive healthcare and the management of chronic disease. In addition, it is estimated by the U. S. Census Bureau that approximately 44 million Americans do not have health insurance. Both of these factors are driving a growing trend towards personal health management, which we believe requires practical, economical and efficient tools to address a widespread, growing need. Our cost effective diagnostic technologies provide convenient, accurate testing as a part of a disease management program and are used for screening for heart disease and diabetes by identifying individuals with elevated cholesterol and blood glucose levels and monitoring the ongoing condition of people with heart disease and diabetes whose treatment programs may involve long-term, complex drug therapies.

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

We also sell our products to the health promotion market, which includes a variety of venues such as corporate wellness programs, fitness centers, health promotion service providers, community health centers, public health programs, the United States military and other independent screeners. In fiscal year 2004, sales of our products to the health promotion market represented 32% of our revenue. Sales of our products to international markets represented 14% of revenue in fiscal year 2004. While a majority of such sales are in Europe, we are expanding into Asia, the Middle East and Latin America. See Note 12 of the consolidated financial statements for details on our international revenue.

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

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

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Market Overview

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

High cholesterol is a significant contributing factor to cardiovascular disease, which remains the leading cause of death in the United States and kills more people than the next five diseases combined. Heart disease is also the leading cause of death among diabetics.

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

The American Heart Association estimates that more than 64 million people suffer from some form of cardiovascular disease, which is the leading cause of death of adults in the United States.

Heart disease is the leading cause of death in people with type 2 diabetes, which has a death rate from heart disease which is two to four times higher than for those who do not have diabetes.

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

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

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

Our Strategy

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

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

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

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

Increase Market Penetration. We intend to further penetrate the physician office laboratory and health promotion markets by increasing the number of installed LDX Analyzers both domestically and internationally through our network of over 85 distributors. We continue to implement marketing and related programs to increase awareness of the advantages of the LDX System among healthcare providers and third party payors.

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

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

Products and Products Under Development

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

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

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

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Overview of the Cholestech LDX System

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

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

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

The LDX Analyzer

Revenue from the LDX Analyzer represented 8%, 9% and 11% of total revenue in fiscal year 2004, fiscal year 2003 and fiscal year 2002, respectively. The LDX Analyzer is a patented, four-channel, reflectance photometer that measures the amount of light reflected from the reaction surfaces of a test cassette and incorporates a microprocessor with built-in software. The LDX Analyzer contains a drawer for insertion of the cassette, three buttons for user activation and a liquid crystal display to present the test results. Using the information and instructions encoded on the cassette s magnetic strip, the LDX Analyzer s built-in microprocessor regulates the reaction conditions, controls the optical measurements of analyte concentrations on the cassette s reaction pads, executes the required calculations and, within five minutes, displays the results on the liquid crystal display. The results are displayed as a numerical value of the level of the analyte tested and can be transferred to a printer, computer or computer network.

The built-in software calculates the numeric values of the test results and is contained in a removable read only memory software pack mounted in an access well on the bottom of the LDX Analyzer. We upgrade the software as new products are developed, allowing healthcare providers to easily replace the existing read only memory pack with a new pack containing upgraded software. The LDX Analyzer, along with a printer, accessories and starter pack, comprises a LDX System and currently has a domestic list price of $1,995.

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Cassette Products

Revenue from cassette products represented 81%, 79% and 82% of total revenue in fiscal year 2004, fiscal year 2003 and fiscal year 2002, respectively. Our product line of single-use, disposable test cassettes for the LDX System incorporates patented and licensed technology for distributing precisely measured plasma to up to four reaction pads for simultaneous testing. Each cassette has three parts: a main body that contains the sample well into which the blood sample is dispensed, a reaction bar where plasma is transferred for analysis and a magnetic strip encoded with test instructions and lot specific calibration information for the various chemistries on the reaction pads. Capillary action draws a drop of blood through a separation medium within the cassette, stopping the cellular components of the blood while transferring a small volume of plasma to the cassette s reaction pads. When the plasma comes into contact with the reaction pads, the dry chemistry reacts with the analytes in the plasma, producing color. The intensity of color developed indicates the concentration of the analytes in the plasma. The magnetic strip contains information needed by the LDX Analyzer to convert the reflected color reading into a concentration level for the accurate measurement of the analytes being tested. As a result of this automatic process, the healthcare provider does not have to interpret any color reaction, relate a reading to a separate chart or input calibration information. Our available test cassettes range in current domestic list price from $3.95 to $11.25 per cassette and include up to six results per cassette.

Overview of the Cholestech GDX System

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

The GDX Analyzer

The GDX Analyzer uses a photometer that measures the amount of light transmitted through the reaction solutions. The GDX Analyzer contains a receptacle for insertion of the cartridge, three buttons for user activation and a liquid crystal display to present user-guiding icons and the test results. The GDX Analyzer s built-in microprocessor regulates the reaction conditions, controls the optical measurements of analyte concentrations in the cartridge s reaction solutions, executes the required calculations and, within five minutes, displays the results on the liquid crystal display. The results are displayed as a numerical value of the A1C level and can be transferred to a printer, computer or computer network. The GDX Analyzer is certified by the National Glycohemoglobin Standardization Program. The GDX Analyzer, along with accessories, comprises a GDX System and currently has a domestic list price of $895.

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Cartridge Product

The GDX System s A1C single-use, disposable test cartridges use a well-established boronate affinity chromatography technique to separate the 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.

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

Product	Regulatory Status(1)
Instrument	
LDX Analyzer	FDA cleared; CLIA waived
GDX Analyzer	FDA cleared, CLIA waived
Endo-Pat 2000	FDA cleared
Cassette Products	
Current	
Lipid Profile (Lipid) (Total cholesterol/ High density lipoproteins/ Calculated low density lipoproteins/ Triglycerides)	FDA cleared; CLIA waived
Lipid Profile plus Glucose (Lipid/ GLU)	FDA cleared; CLIA waived
Total Cholesterol and Glucose (TC, GLU)	FDA cleared; CLIA waived
Total Cholesterol/ High Density Lipoproteins/ Glucose (TC, HDL, GLU)	FDA cleared; CLIA waived
Total Cholesterol and High Density Lipoproteins (TC, HDL)	FDA cleared; CLIA waived
Total Cholesterol (TC)	FDA cleared; CLIA waived
Alanine Aminotransferase (ALT)	FDA cleared, CLIA waived
Under Development(2)	
Aspartate Aminotransferase (AST)	FDA cleared
High Sensitivity C-Reactive Protein (hs-CRP)	
Lipid Profile/ Alanine Aminotransferase (Lipid/ ALT)	No regulatory filing required
In Feasibility Studies(3)	
Total Bilirubin (Tbil)	Not filed or applied
Alkaline Phosphate (ALP)	Not filed or applied
Gamma Glutamyl Transferase (GGT)	Not filed or applied
Creatine Kinase (CK)	Not filed or applied
Blood Urea Nitrogen (BUN)	Not filed or applied
Creatinine	Not filed or applied
Potassium (K)	Not filed or applied
Uric Acid	Not filed or applied
Direct Low Density Lipoproteins (LDL)	Not filed or applied
Hemoglobin A1c (A1C)	Not filed or applied
Cartridge Product	
Hemoglobin A1c (A1C)	FDA cleared; CLIA waived

(1) FDA means the United States Food and Drug Administration; FDA cleared means the product has received clearance pursuant to Section 510(k) of the Food, Drug and Cosmetics Act of 1938, as amended. CLIA waived means the Food and Drug Administration has granted our application to classify the product as having waived status with respect to the Clinical Laboratory Improvement Amendments.

(2) Products under development are those that have completed the feasibility phase of the commercialization process and have begun the development phase. During the development phase, manufacturing processes are developed and defined, initial lots are made using those manufacturing processes and performance against product

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specifications is demonstrated. The products under development are then transferred to manufacturing prior to launch.
(3) Products in the feasibility phase of our commercialization process are studied to determine the compatibility of the reagents with the single use test cassette and preliminary data is generated to indicate if the reagents can perform to preliminary specifications.

Current Cassette and Cartridge Products

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

Lipid Profile. We offer a lipid profile cassette, which directly measures TC, HDL and triglycerides. This cassette meets all of the screening and monitoring guidelines recommended by the NIH guidelines. In addition, the lipid profile cassette calculates estimated values for LDL and the ratio of TC to HDL. The development of cardiovascular disease has been associated with three lipoprotein abnormalities: high levels of LDL, high levels of very low density lipoproteins (VLDL) and low levels of HDL. LDL, the major carrier of cholesterol and VLDL, a major carrier of triglycerides in the blood, have been shown to be associated with deposits of plaque on the arterial wall. High levels of triglycerides can also lead to development of such plaque. Accumulation of this plaque leads to a narrowing of the arteries and increases the likelihood of cardiovascular disease. The lipid profile cassette thus performs multiple tests in the diagnostic screening and ongoing therapeutic monitoring of individuals who have high LDL levels or who exhibit two or more other cardiovascular disease risk factors. NCEP guidelines recommend that healthcare providers perform two lipid profiles, one to four weeks apart, before initiating lipid lowering drug therapy.

Lipid Profile plus Glucose Panel, Total Cholesterol and Glucose Panel, and Total Cholesterol/ High Density Lipoproteins/ Glucose Panel. Recognizing the relationship between diabetes and abnormal lipid levels, we developed a blood glucose test for the LDX System and combined it with each of its three lipid related test panels. The resulting panels provide input used in the diagnostic screening and therapeutic monitoring of patients with diabetes, whether or not they are aware they are diabetic, as well as individuals who may be at risk of cardiovascular disease.

Total Cholesterol and High Density Lipoproteins Panel. The total cholesterol (TC) and high density lipoproteins (HDL) panel is the recommended test under the current NIH guidelines if the individual being screened has not fasted. HDL particles circulate in the blood and can pick up cholesterol from arteries and carry it to the liver for elimination from the body. HDL is sometimes called good cholesterol because of this function. This panel also calculates the ratio of TC to HDL, a recognized measure of cholesterol induced cardiac risk.

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

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

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alanine aminotransferase (ALT) test combined with our lipid profile allows healthcare providers to monitor both the impact of and potential adverse side effects on the liver from lipid lowering and diabetic therapies.

A1C. Hemoglobin A1c (A1C) is recommended by the American Diabetes Association for long-term management of glycemia in diabetes mellitus. Patients being treated to lower their blood glucose levels are tested from two to four times per year depending on whether their A1C levels are stable or their therapy is changing.

Cassette Products Under Development

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

Aspartate Aminotransferase. Patients undergoing certain drug therapies must be monitored for increases in certain enzymes that are associated with liver damage. We received 510(k) clearance from the FDA for our AST test in September 2003 and we have applied for a CLIA waiver for this product. The availability of an aspartate aminotransferase (AST) test in conjunction with our ALT test would allow healthcare providers to monitor both the impact of and potential adverse side effects on the liver from lipid lowering and diabetic therapies.

High Sensitivity C-Reactive Protein. The high sensitivity C-Reactive Protein (hs-CRP) test measures, by immunoassay, the amount of HS-CRP present in a patient sample. Recent research has demonstrated that HS-CRP is a marker of coronary artery inflammation that is an early step in the development of a heart attack. Studies have shown that hs-CRP is an independent risk factor for coronary heart disease and when used in conjunction with certain other risk factors, such as total cholesterol and HDL-cholesterol, is useful in predicting future cardiovascular events.

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

Cassette Products in Feasibility Studies

We are in various stages of feasibility studies for new cassettes that would expand our product line for diagnostic testing. We may develop additional tests depending on the progress of our existing development efforts and available resources.

Hepatic Panel

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

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

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

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

Drug Monitoring Panel

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

Renal Panal

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

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

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

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

Individual Test Cassettes

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

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

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Other Platforms

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

Strategic Relationships

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

Distribution

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

ImpactHealth.com, Inc.

ImpactHealth.com, Inc. (ImpactHealth) is a nationwide provider of clinical testing services that markets services and self-testing products to the pharmaceutical, managed care, employer and health product retail industries. In December 2002, ImpactHealth acquired certain assets and obligations of WellCheck, a testing services business which was formally 100% owned by us. In connection with the acquisition, we have entered into a three-year renewable supply agreement involving the purchase of the LDX System and test cassettes by ImpactHealth on an exclusive basis.

Itamar Medical

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

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Marketing Programs

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

Sales and Marketing

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

Our sales and marketing strategy includes increasing penetration into the physician office laboratory and health promotion markets and leveraging our installed base of LDX and GDX Analyzers. Over the past year, we expanded the number of domestic sales and field technical service associates. We plan to dedicate a significant portion of our sales and marketing efforts to educate current and potential customers about the clinical and economic benefits of diagnostic screening and therapeutic monitoring and about new test cassettes as they become available for distribution. We also plan to continue to cultivate strategic relationships with development partners, pharmaceutical companies and distributors. We intend to leverage the technology, customer base, marketing power and distribution networks of these partners to accelerate market penetration and increase cassette usage. Our current marketing activities are primarily focused on:

Physician Office Laboratories. We have entered into nonexclusive distribution agreements with five national medical products distributors, Cardinal Health, Inc., Fisher Scientific International, Inc., McKesson Corporation, Physician Sales and Service Inc. and Henry Schein, Inc., which together have more than 2,500 sales professionals who focus on the United States physician office laboratory market. We have also retained more than 35 regional distributors in the United States. In addition, we and our distributors focus sales and marketing efforts on physicians whose practices include a high incidence of the cholesterol-related diseases targeted by our test cassettes, including cardiologists, lipid clinicians, internists and family practitioners.

Health Promotion. We have ongoing relationships with approximately 15 regional distributors who provide equipment and supplies to customers who conduct diagnostic screening for cholesterol and related lipid levels and diabetes.

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

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Competition

The diagnostic products markets in which we operate are intensely competitive. Our competition consists primarily of clinical and hospital laboratories, as well as manufacturers of bench top analyzers. The substantial majority of diagnostic tests used by physicians and other healthcare providers are currently performed by clinical and hospital laboratories. We expect that these laboratories will compete aggressively to maintain dominance in the market. To achieve broad market acceptance, we must demonstrate that the LDX System and GDX System are attractive alternatives to bench top analyzers and clinical and hospital laboratories. This will require physicians to change their established means of having such tests performed. There can be no assurance that the LDX System and GDX System will be able to compete with these other analyzers and testing services.

Companies with a significant presence in the diagnostic products market, such as Abbott Laboratories, Bayer Diagnostics, Beckman Coulter, Inc. and Roche Diagnostics (a subsidiary of Roche Holdings Ltd.), have developed or are developing analyzers designed for point of care testing. Such competitors also offer broader product lines than us, have greater name recognition than us and offer discounts as a competitive tactic. In addition, several smaller companies, including Polymer Technology Systems, Inc., are currently making or developing products that compete or will compete with us. We believe we currently have a competitive advantage due to (i) the status of the LDX System which is waived under CLIA and can provide a complete lipid profile in accordance with the NIH guidelines in less than five minutes using a single drop of blood; (ii) our ALT test, which is the only ALT test waived under CLIA by the FDA and enables physicians to monitor the potential side effects on the liver from cholesterol lowering drugs and other medications; (iii) the improving breadth of the CLIA waived tests that we can offer our installed base and (iv) our network of over 85 distributors. We expect that our competitors will compete actively to maintain and increase market share and will seek to develop multi-analyte tests that qualify for waiver under CLIA.

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

Manufacturing

We manufacture, test, perform quality assurance on, package and ship our products from our approximately 69,000 square foot facility located in Hayward, California. We maintain control of those portions of the manufacturing process that we believe are complex and provide an important competitive advantage.

LDX Analyzer. The LDX Analyzer incorporates a variety of subassemblies and components designed or specified by us, including an optical element, microprocessors, circuit boards, a liquid crystal display and other electrical components. These components and subassemblies are manufactured by a variety of suppliers and are shipped to us for final assembly and quality assurance. Our manufacturing process for the LDX Analyzer consists primarily of assembly, testing,

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inspection and packaging. Testing consists of a burn-in period, functional tests and integrated system testing using specially produced test cassettes. Our manufacturing process complies with FDA Quality System Requirements, ISO 9001 and TÜV GS Mark guidelines. We believe we can expand our current LDX Analyzer manufacturing capacity as needed.

Cassettes. We purchase chemicals, membranes, plastic parts and other raw materials from suppliers and convert these raw materials, using proprietary processes, into single-use test cassettes. We believe our proprietary processes and custom designed equipment are important components of our cassette manufacturing operations. We have developed core manufacturing technologies, processes and production machinery, including membrane lamination and welding, discrete membrane impregnation, on-line calibration and software control of the manufacturing process. The overall manufacturing process meets FDA Quality System Requirements and in-vitro diagnostic directive, including in process and final quality assurance testing. The majority our cassette production is currently on our high volume manufacturing line. We use a second manufacturing line for research and development purposes and production overflow.

Raw Materials and Quality Assurance. Suppliers provide us with the subassemblies, components and raw materials necessary for the manufacturing of our products. These subassemblies, components and raw materials are inspected and tested by our quality control personnel. We expect the supply of raw materials to be adequate for our current level of business and into the foreseeable future. Our manufacturing facilities are subject to periodic inspection by regulatory authorities. Certain key components and raw materials used in the manufacturing of our products are currently provided by single source vendors and on a purchase order basis. Our quality assurance personnel also perform finished goods quality control and inspection and maintain documentation for compliance with quality systems regulations and other government manufacturing regulations.

Patents and Proprietary Technology

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

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

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

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

There can be no assurance that patent infringement claims will not be asserted against us by other parties in the future, that in such event we will prevail or that we will be able to obtain necessary licenses on reasonable terms, or at all. Adverse determinations in any litigation could subject us to significant liabilities and/or require us to seek licenses from third parties. If we are unable to obtain necessary licenses or are unable to develop or implement alternative technology, we may be unable to manufacture and sell the affected products. Any of these outcomes could have a material adverse effect on our business, financial condition or results of operations.

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

Government Regulation

Food and Drug Administration and Other Regulations

The manufacture and sale of our products are subject to regulation by numerous governmental authorities, principally the United States Food and Drug Administration (the FDA) and corresponding state and foreign regulatory agencies. Pursuant to the Food, Drug and Cosmetics Act of 1938, as amended (the 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

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adherence to quality systems regulations). Class II devices are subject to general controls, pre-market notification and special controls (e.g., performance standards, post-market surveillance and patient registries). Generally, Class III devices are those that must receive pre-market approval from the FDA (e.g., life sustaining, life supporting and implantable devices or new devices which have not been found substantially equivalent to legally marketed devices) and require clinical testing to assure safety and effectiveness.

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

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

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

The FDC Act regulates our quality control and manufacturing procedures by requiring us and our contract manufacturers to demonstrate compliance with quality systems regulations. The FDA monitors compliance with these requirements by requiring manufacturers to register with the FDA, which subjects them to periodic inspections. We were recently inspected by the FDA as part of a routine quality system audit. The State of California also regulates and inspects our manufacturing facilities. We have been inspected twice by the State of California to date and are manufacturing under an issued medical device manufacturer s facility license from the State of California. If any violations of our

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applicable regulations are noted during a FDA, European Notified Body or State of California inspection of our manufacturing facilities or those of our contract manufacturers, the continued marketing of our products could be materially adversely affected.

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

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

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

Clinical Laboratory Improvement Act Regulations

The use of our products in the United States is subject to CLIA, which provides for federal regulation of laboratory testing, an activity also regulated by most states. Laboratories must obtain either a registration certificate from CMS, register with an approved accreditation agency or obtain a state license in a state with a federally approved license program. The CLIA regulations seek to ensure the quality of medical testing. The three primary mechanisms to accomplish this goal are daily quality control requirements to ensure the accuracy of laboratory devices and procedures, proficiency testing to measure testing accuracy and personnel standards to assure appropriate training and experience for laboratory workers. CLIA categorizes tests as waived, or as being moderately complex or highly complex on the basis of specific criteria. To successfully commercialize tests that are currently under development, we believe it will be critical to obtain waived classification for such tests under CLIA, because CLIA waiver allows healthcare providers to use the LDX System at a lower cost.

Third Party Reimbursement

In the United States, healthcare providers such as hospitals and physicians that purchase products such as the LDX System and single-use test cassettes generally rely on third party payors, including private health insurance plans, federal Medicare, state Medicaid and managed care organizations, to reimburse all or part of the cost of the procedure in which the product is being used. Our ability to

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commercialize our products successfully in the United States will depend in part on the extent to which reimbursement for the costs of tests performed with the LDX System and related treatment will be available from government health authorities, private health insurers and other third party payors. For example, in December 2003, provisions for cholesterol and diabetes screening, which are expected to be implemented in January 2005, were included in the federal Prescription Drug and Medicare Improvement Act of 2003. Third party payors can affect the pricing or the relative attractiveness of our products by regulating the maximum amount of reimbursement provided by such payors for testing services. Reimbursement is currently not available for certain uses of our products in particular circumstances. For example, tests performed in the health promotion market are generally not subject to reimbursement. Pharmacists also face blocking state legislation in a number of states, which precludes them from accessing federally available reimbursement codes and practices. Third party payors are increasingly scrutinizing and challenging the prices charged for medical products and services. Decreases in reimbursement amounts for tests performed using our products may decrease amounts physicians and other practitioners are able to charge patients, which in turn may adversely affect our ability to sell our products on a profitable basis. In addition, certain healthcare providers are moving toward a managed care system in which such providers contract to provide comprehensive healthcare for a fixed cost per patient. Managed care providers are attempting to control the cost of healthcare by authorizing fewer elective procedures, such as the screening of blood for chronic diseases.

We are unable to predict what changes will be made in the reimbursement methods used by third party payors. The inability of healthcare providers to obtain reimbursement from third party payors, or changes in third party payors policies toward reimbursement of tests using our products, could have a material adverse effect on our business, financial condition and results of operations. Given the efforts to control and reduce healthcare costs in the United States in recent years, there can be no assurance that currently available levels of reimbursement will continue to be available in the future for our existing products or products under development.

In 1991, the Health Care Finance Administration adopted regulations providing for the inclusion of capital related costs in the prospective payment system for hospital inpatient services under which most hospitals are reimbursed by Medicare on a per diagnosis basis at fixed rates unrelated to actual costs, based on diagnostic related groups. Under this system of reimbursement, equipment costs generally are not reimbursed separately, but rather are included in a single, fixed rate, per patient reimbursement. Medicare reform legislation requires CMS to implement a prospective payment system for outpatient hospital services as well. This system may also provide for a per-patient fixed rate reimbursement for outpatient department capital costs. We believe these regulations place more pressure on hospitals operating margins, causing them to limit capital expenditures. These regulations could have an adverse effect on us if hospitals decide to defer obtaining medical equipment as a result of any such limitation on their capital expenditures. The Medicare legislation also requires CMS to adopt uniform coverage and administration policies for laboratory tests. We are unable to predict what adverse impact on us, if any, additional government regulations, legislation or initiatives or changes by other payors affecting reimbursement or other matters that may influence decisions to obtain medical equipment may have.

We believe the escalating cost of medical care and services has led to and will continue to lead to increased pressures on the healthcare industry, both foreign and domestic, to reduce the cost of care and services, including products offered by us. In addition, market acceptance of our products in

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international markets is dependent, in part, on the availability of reimbursement within prevailing healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country, and include both government sponsored healthcare and private insurance. There can be no assurance in either domestic or foreign markets that third party reimbursement and coverage will be available or adequate, that current reimbursement amounts will not be decreased in the future or that future legislation, regulation or reimbursement policies of third party payors will not otherwise adversely affect the demand for our products or our ability to sell our products on a profitable basis.

Product Liability and Insurance

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

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

Employees

As of March 26, 2004, we employed 199 full-time associates. There were 85 employees in manufacturing, 55 employees in sales and marketing, 32 employees in administration and 27 employees in research and development. None of our associates are covered by a collective bargaining agreement, and management considers relations with employees to be excellent.

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Executive Officers

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

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

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

William W. Burke has served as our Corporate Vice President of Finance, Chief Financial Officer, Treasurer and Secretary since March 2001. From August 1998 to March 2001, Mr. Burke was a Managing Director in Bear, Stearns & Co. Inc. s investment banking department. He was a Managing Director in Everen Securities, Inc. s investment banking group from May 1991 to May 1995 and January 1998 to August 1998. From May 1995 to January 1998, he served as Managing Director and Director of Healthcare Investment Banking for Principal Financial Securities, Inc., which was acquired by Everen in January 1998. Mr. Burke holds a Bachelor of Business Administration degree in Finance from the University of Texas at Austin and a Masters of Business Administration degree from the University of Pennsylvania s Wharton Graduate Business School.

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

Terry L. Wassmann has served as our Vice President of Human Resources since March 2000. Before joining Cholestech, Ms. Wassmann served as Staff Relations Manager with Robert Half International from July 1999 to March 2000. From February 1986 to December 1999, Ms. Wassmann was employed by Boehringer Mannheim where she held numerous positions within the Human Resources

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department, including the Director of Human Resources of the Indiana and California based Diagnostics Division. Ms. Wassmann has been awarded the SPHR title from the Society of Human Resource Management.

Donald P. Wood has served as our Vice President of Operations since April 2003. From July 2001 to March 2003, Mr. Wood served as Vice President of Bone Health, a business unit of Quidel Corporation and was responsible for Bone Health Product Operations, Device Research and Development, and Sales and Marketing. He also served as Quidel s Vice President of Ultrasound Operations from August 1999 to July 2001. Prior to joining Quidel, Mr. Wood was the Director of Ultrasound Operations for Metra Biosystems Inc. from July 1998 to August 1999. He also served as its Director of Operations from October 1995 to July 1998. Mr. Wood also served as Senior Director of Operations for BioChem Pharma Inc. from July 1994 to October 1995 and Mr. Wood held numerous positions within operations for Serono Diagnostics Inc. from 1980 to July 1994. Mr. Wood holds a Bachelor of Science degree in Business Administration from Bloomsburg University.

Dr. Thomas E. Worthy has served as our Vice President, Development and Regulatory Affairs since August 1999. From April 1998 to August 1999, he served as our Director of Technical Affairs. Before joining Cholestech, Dr. Worthy held Director of Research and Development positions at Microgenics Corporation, a division of Boehringer Mannheim Corporation, from January 1980 to April 1998, and at MetPath, Inc. from May 1981 to February 1988. He holds a Doctor of Philosophy degree in Radiation Biology from the University of Tennessee, a Master of Science degree in Microbiology from Northern Illinois University and a Bachelor of Arts degree in Biology from Albion College.

Available Information

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

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

ITEM 2: PROPERTIES

Our offices are located in a leased 69,000 square foot facility in Hayward, California. Our facilities contain approximately 10,000 square feet of warehouse space, 8,000 square feet of manufacturing space, 4,000 square feet of laboratory space and the balance devoted to marketing and administrative and common areas. Our lease pertaining to this facility expires in April 2007, with an option to extend

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the lease for an additional three-year term. We expect that our current leased facilities will be sufficient for our needs over the next 12 months.

ITEM 3: LEGAL PROCEEDINGS

On August 2, 2002, N.V. Euromedix (Euromedix) filed suit against us in the Commercial Court in Leuven, Belgium (No. F5700-02), seeking damages for the wrongful termination of an implied distribution agreement with our company for Europe and parts of the Middle East. On November 7, 2002, the court dismissed the suit. On December 31, 2002, Euromedix filed suit against us in the Commercial Court in Leuven, Belgium (No. B/02/00044), seeking damages in the amount of approximately 3.5 million for the wrongful termination of an implied distribution agreement with our company for Europe and parts of the Middle East. At the introductory hearing on April 1, 2003, the case was sent to the general docket and there have been on further developments. We believe this claim is without merit and intend to continue to defend the claim vigorously.

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

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

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

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On March 3, 2003, Roche Diagnostics Corporation and Roche Diagnostics GmbH filed suit against us in the United States District Court for the Southern District of Indiana (Indianapolis) (No. 03-CV-0303-LJM-WTL), seeking a preliminary and permanent injunction, damages and attorneys fees for patent infringement. We were served with the suit on June 30, 2003. The complaint alleges that we are violating three Roche U.S. patents for HDL. On July 21, 2003, we filed an answer and counter claim with the U.S. District Court for the Southern District of Indiana.

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

On December 23, 1999, Roche filed suit against us and two of our distributors, Health Care Solutions AG and Euromedix N.V./ SA, in the Canton Court of the Canton Zug in Zug, Switzerland (No. ES580/1999), seeking a cease and desist order barring us from selling HDL assay single-use test cassettes in Switzerland. The complaint alleges that we violated a Roche European patent for HDL. On July 11, 2000, the court denied Roche s request for an injunction and ordered it to pay a portion of our legal fees. On May 2, 2002, in response to our motion, the court ruled that it did not have local jurisdiction over the matter and ordered Roche to pay our legal fees. Roche subsequently appealed the May 2, 2002 decision by the Canton Court of the Canton Zug. On October 7, 2002, the Swiss Federal Tribunal referred the matter back to the Canton Court but rejected the jurisdiction aspect of Roche s appeal.

In January 2000, Roche filed suit against us and two of our distributors, Micro-Medical GmbH and Euromedix N.V./ SA, in the District Court in Dusseldorf, Germany (No. 4aO4/00), seeking a cease and desist order barring us from selling HDL single-use test cassettes in Germany. The complaint alleges we violated a Roche German priority patent for HDL by selling our single-use test cassette containing a HDL assay in Germany. On December 4, 2001, a hearing was held in Dusseldorf, Germany at which witnesses for Roche and our company testified. On October 29, 2002, the District Court held a hearing on the merits of the case. The court rendered its decision on December 19, 2002, ruling that (i) we are not allowed to further distribute HDL test cassettes which correspond to the German Roche patent, (ii) our distributors must destroy HDL products in their possession, (iii) we and our distributors are subject to unspecified damages based on all sales which occurred in Germany since December 8, 1995 and (iv) we and our distributors must pay the legal fees of the litigation. On January 10, 2003, we appealed this ruling with the Appeal Court in Dusseldorf.

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

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

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

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

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

None.

PART II

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

Our common stock is quoted on the NASDAQ National Market under the symbol CTEC. On March 26, 2004, the last reported sale price for our common stock on the NASDAQ National Market was $8.55 per share. The following table sets forth the quarterly high and low trading prices for our common stock as reported by the NASDAQ National Market for the periods indicated.

	High	Low
FISCAL YEAR 2003		
First Quarter	$20.05	$9.25
Second Quarter	15.30	8.55
Third Quarter	11.45	4.35
Fourth Quarter	8.80	6.00
FISCAL YEAR 2004		
First Quarter	$12.89	$7.28
Second Quarter	11.11	7.30
Third Quarter	9.31	6.20
Fourth Quarter	9.39	6.72

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

Dividend Policy

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

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

Equity Compensation Plans

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

ITEM 6: SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated financial data should be read in conjunction with our consolidated financial statements and notes thereto and Management s Discussion and Analysis of Financial Condition and Results of Operations. The following selected consolidated statement of operations data for the fiscal years ended March 26, 2004, March 28, 2003 and March 29, 2002 and the selected consolidated balance sheet data as of March 26, 2004 and March 28, 2003 are derived from, and qualified by reference to, the audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. Amounts for all periods in this Annual Report on Form 10-K, including the historical statements and related notes, have been reclassified to reflect the presentation of discontinued operations. The selected consolidated statement of operations data for the fiscal years ended March 30, 2001 and March 31, 2000 and the consolidated balance sheet data as of March 29, 2002, March 30, 2001 and March 31, 2000 have been derived from our audited consolidated financial statements not included in this Annual Report. These historical results are not necessarily indicative of the results of operations to be expected from any future period.

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

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

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

(1) Our fiscal year is a 52-53 week period ending on the last Friday in March. All fiscal years referenced in this Annual Report on Form 10-K consisted of 52 weeks, except fiscal year 2000, which consisted of 53 weeks. For convenience, we have indicated in this Annual Report on Form 10-K that our fiscal year ends on March 31 and refer to the fiscal year ended March 26, 2004 as fiscal 2004, March 28, 2003 as fiscal year 2003, March 29, 2002 as fiscal year 2002, March 30, 2001 as fiscal year 2001 and the fiscal year ended March 31, 2000 as fiscal year 2000.

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

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

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

Introduction

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

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

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

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

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

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

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

Overview

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

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

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

Recent Events

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

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

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

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

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

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

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

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

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

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

Results of Operations

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

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

Fiscal Year Ended	March 26, 2004 Amount	March 26, 2004 % of sales	March 28, 2003 Amount	March 28, 2003 % 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)	16
Gain (loss) from discontinued operations	34		(1,377)	(3)	1,411	102
Loss from sale of discontinued operations			(4,445)	(9)	4,445	100
Net income (loss)	$ 8,707	17%	$ 4,893	10%	$ 3,814	78%

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

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

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

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

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

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

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

Operating Expenses

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

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

Research and Development. Our research and development expenses include salaries, bonuses, expenses for outside services, supplies and amortization of capital equipment. Research and development expenses increased 16% to $3.2 million in fiscal year 2004 from $2.7 million in fiscal year 2003. The increases in wages and related, outside services and development materials all relate to increased efforts to develop new test cassette products for use on our LDX Analyzer. We expect our costs for new product development to remain constant or increase slightly during fiscal year 2005 as we prepare new products for launch into the marketplace.

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

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

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

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

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

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

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

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

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

Loss on Sale of Discontinued Operations. In fiscal year 2003, we completed the sale of certain assets and the assignment of certain obligations of our subsidiary WellCheck. We incurred a charge of $4.4 million reflecting the write-off of certain fixed assets, goodwill, compensation expenses for staff, professional services, the termination of property leases and other liabilities in excess of the $250,000 note receivable. We had no such charge in fiscal year 2004.

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

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

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

LDX Analyzer unit sales decreased 5% worldwide in fiscal year 2003 compared to fiscal year 2002. The decline was mainly in the health promotion market in which unit sales decreased 10%. International unit sales decreased 21%. However, unit sales in the physician office laboratory market increased 29%.

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

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

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

Operating Expenses

Sales and Marketing. Our sales and marketing expenses include salaries, commissions, bonuses, expenses for outside services related to marketing programs and travel expenses. Sales and marketing expenses increased 27% to $11.7 million in fiscal year 2003 from $9.2 million in fiscal year 2002. Sales and marketing expenses increased to 24% of sales in fiscal year 2003 from 22% in fiscal year 2002. Wages, benefits and other compensation costs increased $1.1 million, or 29%, to $5.0 million in fiscal year 2003. This increase was attributable to the hiring of 11 additional staff members. Product marketing costs, which include sample goods, distributor relations, product design and trade show expense, increased $904,000 or 33%.

Research and Development. Our research and development expenses include salaries, bonuses, expenses for outside services, supplies and amortization of capital equipment. Research and development expenses increased 24% to $2.7 million in fiscal year 2003 from $2.2 million in fiscal year 2002. Research and development expenses as a percentage of revenue increased to 6% in fiscal year 2003 from 5% in fiscal year 2002. This increase was attributable to the consumption of development materials and other related costs which increased $252,000 due primarily to our efforts to develop a new immunoassay test product. Additionally, wages and other related costs increased $129,000 due to staffing increases.

General and Administrative. Our general and administrative expenses include salaries and benefits, as well as expenses for outside professional services including information services, legal, accounting, insurance and costs associated with our board of directors. General and administrative expenses increased 9% to $7.0 million in fiscal year 2003 from $6.4 million in fiscal year 2002. The increase in such spending was attributable to $591,000 of restructuring cost incurred in December 2002, which included wages, severance and other related costs for two executives and two staff members whose employment was terminated as a result of our management restructuring associated with the divestiture of our WellCheck testing services business. As a percent of total revenue, general and administrative expenses decreased to 14% in fiscal year 2003 from 15% in fiscal year 2002.

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

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

Interest and Other Income, Net. Interest income reflects income from the investment of cash balances and marketable securities, net of expenses. Interest income decreased 2% to $438,000 in fiscal year 2003 from $449,000 in fiscal year 2002. This decrease was primarily the result of reduced yields on cash equivalents and marketable securities, together with higher bank service fees. Realized gains from sales of marketable securities were $121,000 in fiscal year 2003 and $11,000 in fiscal year 2002.

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

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

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

Loss on Sale of Discontinued Operations. In fiscal year 2003, we completed the sale of certain assets and the assignment of certain obligations of our subsidiary WellCheck. We incurred a charge of $4.4 million reflecting the write-off of certain fixed assets, compensation expenses for staff, professional services, the termination of property leases, and other liabilities in excess of the $250,000 note receivable. We had no such charge in fiscal year 2002

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Liquidity and Capital Resources

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

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

We have financed our operations primarily through the sale of equity securities, including employee stock option exercises, and net cash provided by operations. From our inception to March 26, 2004, we have raised $84.3 million in net proceeds from equity financings. In addition to these amounts, we have available a $4.0 million revolving bank line of credit agreement which was renewed in July 2003 and will expire in September 2004. While the agreement is in effect, we are required to deposit assets with a collective value, as defined in the line of credit agreement, equivalent to no less than 100% of the outstanding principal balance. Amounts outstanding under the line of credit bear interest at either our choice of 0.5% below the bank s prime rate or 1.75% above the LIBOR rate, depending on the payment schedule. The line of credit agreement expires on September 1, 2004. We did not borrow under this line of credit during fiscal year 2004. As a result, there were no limitations on our deposited assets.

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

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

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

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

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

Contractual Obligations

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

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

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

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

We expect that cash generated from our projected revenue, existing cash, cash equivalents and marketable securities and proceeds from the exercise of employee stock options will enable us to maintain our current and planned core operations for at least the next 12 months. Excluding the Roche settlement in fiscal year 2004, we have achieved positive net cash provided from operations for fiscal years 2000 through 2004 and we expect to continue to generate cash from operations for the foreseeable future.

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

Off-Balance Sheet Arrangements

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

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Quarterly Financial Data

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

Critical Accounting Policies

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

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

Revenue Recognition

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

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services upon completion of the services to be performed under contract when all obligations are satisfied, and collection is reasonably assured. If all conditions to recognize revenue are not met, we are required to defer revenue recognition.

Allowance for Bad Debts

We maintain an accounts receivable allowance for an estimated amount of losses that may result from a customer s inability to pay for product purchased. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required, which could adversely affect our operating results. In the past, reserves, adjustments to reserve estimates and write-offs have not been significant.

Inventory Valuation