CHOLESTECH CORPORATION
Form 10-K
June 18, 2002

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UNITED STATES OF AMERICA 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 29, 2002

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. 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 March 28, 2002 as reported on the NASDAQ National Market, was approximately $197,350,000. 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 in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of May 31, 2002, the registrant had outstanding 13,382,498 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 2002 Annual Meeting of Shareholders to be held August 14, 2002.

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CHOLESTECH CORPORATION

ANNUAL REPORT ON FORM 10-K

For The Fiscal Year Ended March 29, 2002

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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, anticipate believes, estimates, predicts, potential or continue or the negative of these terms or other comparable terminology. Although we believe that expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Moreover, neither any other person nor we assume responsibility for the accuracy and completeness of such statements. Important factors that may cause actual results to differ from expectations include those discussed in Factors Affecting Future Operating Results beginning on page 40 in this document.

We are incorporated under the laws of the State of California. 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

General

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

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

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

Diagnostic Products currently manufactures and markets the LDX System, including the LDX Analyzer and a variety of single-use test cassettes, in the United States of America, Europe, Asia and South America. The LDX System 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.

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WellCheck, funded by third-party sponsors, uses the Cholestech LDX System to provide promotional health screenings for leading pharmaceutical, consumer product and corporate wellness clients throughout the United States of America in convenient consumer venues. These testing service activities result in additional sales of test cassettes manufactured by our Diagnostic Products business. WellCheck s professionals provide high quality services and offer test event expertise to both event sponsors and consumers. As part of our testing services, we utilize our proprietary TEAMS technology which automates registration, data acquisition and information management at testing events and provides participants with a personalized risk assessment for heart disease. Additionally, through this personalized risk assessment product, WellCheck provides its pharmaceutical, consumer product and other customers with analyses and insights into their targeted populations. WellCheck has developed its technology with the input of various authorities on health information privacy practices. TEAMS incorporates procedures that meet state and federal legislation, such as HIPAA, concerning the use of protected health information.

Substantially all of WellCheck s revenue is derived from promotional programs with major pharmaceutical companies marketing lipid-lowering statin drugs. We believe an opportunity exists to further expand our testing services business in the promotional and corporate wellness markets, along with other convenient venues which broaden consumer access to testing while assisting pharmaceutical and consumer product companies in customer acquisition. Our goal is to expand our testing services, thereby increasing sales of test cassettes manufactured by our Diagnostic Products business.

Our ongoing investment relating to WellCheck may result in continuing negative cash flows for this business unit. We intend to continue to make significant expenditures in sales, marketing, development and other areas to develop this business. The amount and timing of expenditures will have an impact on our ability to maintain profitability and positive cash flows.

As WellCheck s third party sponsorships evolve, the number of testing events and tests performed will vary and revenue will fluctuate. In an effort to diversify our customer base, we have established relationships with various third party sponsors for the upcoming fiscal year, but the exact timing and level of some of these sponsorships have not yet been finalized. Additionally, WellCheck s revenue will be influenced by seasonality. During the last two months of the calendar year, promotional testing decreases significantly as sponsors budgets become fully spent. In addition, people typically pursue other interests and are less focused on chronic health issues during this time period.

Market Overview

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

High cholesterol is a significant contributing factor to heart disease, which remains the number one cause of death in America and kills more people than the next seven diseases combined. Heart disease is also the leading cause of death among diabetics.

The American Heart Association estimates that more than 61 million people suffer from some form of cardiovascular disease, which is the leading cause of death of adults in the United States of America and resulted in over 958,000 deaths in 1999.

Based on the evidence of scientific studies, the National Cholesterol Education Program (NCEP) expert panel and the National Institutes of Health (NIH) in May 2001 issued new

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guidelines which are expected to substantially increase the number of Americans being treated for high cholesterol. Numerous research studies substantiate that reducing high cholesterol levels significantly reduces the risk of a coronary event by 31%.

According to the NIH, the new guidelines are expected to raise the number of Americans on therapeutic lifestyle changes, such as dietary treatment, from about 52 million to about 65 million and nearly triple the number prescribed a cholesterol-lowering drug from about 13 million to about 36 million.

Diabetes is estimated to afflict approximately 17 million people in the United States of America, over a third of whom have not yet been identified as being diabetic.

Heart disease is the leading cause of diabetes-related deaths. Individuals with diabetes have a two to four times higher risk of having cardiovascular events than individuals without diabetes.

The estimated cost in the United States for 2002 of coronary heart disease and diabetes is $210 billion.

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

identify at risk patients at convenient testing venues;

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

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

enable consumers to take a more active role in their personal health management.

Target Markets

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

physician office laboratories, which are operated by physicians or groups of physicians. The physician office laboratory market consists of approximately 97,000 sites that are registered with the Centers for Medicare & Medicaid Services (CMS) (formerly the Health Care Finance Administration), approximately 44,000 of which are registered to perform only tests that have been waived under the Clinical Laboratory Improvement Amendments (CLIA waived);

health promotion sites, which include a variety of locations such as corporate wellness programs, fitness centers, health promotion service providers, community health centers, public health programs, the United States of America military and other independent screeners; and

consumer events such as promotional sporting and social events and retail venue events.

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Our Strategy

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

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

Increase Market Penetration. We intend to further penetrate the physician office laboratory and health promotion markets by increasing the number of installed LDX Analyzers both domestically and internationally through our network of over 70 distributors. We continue to implement marketing and related programs to increase awareness of the advantages of the LDX System among healthcare providers, third party payors and consumers. In addition, we have entered into strategic relationships with major pharmaceutical companies to promote preventive care testing with the LDX System as an important component of the management of cholesterol-related disease.

Expand Testing Technology. We intend to extend our range of multi-analyte, single-use, disposable cassettes to address additional diagnostic tests to screen for and manage chronic disease. Our current research and development efforts include the planned introduction of a new test cassette that combines our lipid profile and ALT tests. In addition, we are also developing new test cassettes for the measurement of hemoglobin A1c (A1C), an important indicator for assessing the risk of cardiovascular disease.

Expand Cassette Usage. We intend to increase the sale of single-use test cassettes through additional placement of LDX Analyzers, development of new diagnostic tests and broadening the testing venues offered by our WellCheck business.

Expand Manufacturing Capabilities and Efficiencies. We have recently expanded our manufacturing capacity by introducing a third line for the manufacture of cassettes. Additionally, we will seek to introduce manufacturing processes to improve the key performance attributes of our manufacturing operation, including quality, yields and efficiencies.

Expand Salesforce and Distribution Relationships. We intend to augment our sales and marketing efforts by expanding our salesforce as well as our network of over 70 distributors.

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

Further Develop and Diversify Third-Party Sponsorships. We plan to further develop and diversify our strategic relationships to improve penetration of our target markets, particularly with major pharmaceutical companies and other companies interested in health promotion.

Broaden Consumer Testing. We intend to broaden the geographic coverage of our WellCheck testing services by further expanding into the promotional and corporate wellness markets and other convenient venues designed to increase consumer access to such services, and acquiring

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additional regional testing companies. Expansion of our consumer testing will create opportunities for additional sales of test cassettes manufactured by our Diagnostic Products business.

Improve Consumer Access to Testing. We intend to focus on testing outside of clinical or hospital laboratories by providing products and services that improve people s access to cholesterol-related disease risk assessment and management. We believe that more convenient testing will increase the frequency of diagnostic testing and may lead to earlier identification of patients at risk of or suffering from heart disease and diabetes.

Enhance TEAMS Technology. We intend to continue to enhance our software for test event activity management. TEAMS is a proprietary interactive testing program designed to facilitate the operation of a cholesterol-related disease testing event using the LDX System, by providing data acquisition and patient information management to both the event sponsor and the consumer.

Products and Products Under Development

We offer a variety of products and services in our Diagnostic Products and WellCheck businesses. We also have products currently under development.

Diagnostic Products

Diagnostic Products manufactures, markets and develops 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. Diagnostic Products currently manufactures and markets the LDX System, including the LDX Analyzer and a variety of single-use test cassettes, in the United States of America and internationally.

Overview of the Cholestech LDX System

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

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

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

The LDX Analyzer

The LDX Analyzer is a 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.

Cassette Products

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

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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
Cassette Products	
Current	
Lipid Profile (Total cholesterol/ High density lipoproteins/ Calculated low density lipoproteins/ Triglycerides)	FDA cleared; CLIA waived
Lipid Profile plus Glucose	FDA cleared; CLIA waived
Alanine Aminotransferase	FDA cleared, CLIA waived
Total Cholesterol and Glucose	FDA cleared; CLIA waived
Total Cholesterol/ High Density Lipoproteins/ Glucose	FDA cleared; CLIA waived
Total Cholesterol and High Density Lipoproteins	FDA cleared; CLIA waived
Total Cholesterol	FDA cleared; CLIA waived
Under Development(2)	
Lipid Profile/ Alanine Aminotransferase	No regulatory filing required
Aspartate Aminotransferase	Not filed or applied
In Feasibility Studies(3)	
Hemoglobin A1c	Not filed or applied
High Sensitivity C-Reactive Protein	Not filed or applied
Direct Low Density Lipoproteins	Not filed or applied

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

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

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

Current Cassette Products

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

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

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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.

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

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

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

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

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.

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.

Aspartate Amino Transferase. Patients undergoing certain drug therapies must be monitored for increases in certain enzymes that are associated with liver damage. The availability of an aspartate amino transferase (AST) test in conjunction with the our ALT test would allow additional healthcare providers to monitor both the impact of and potential adverse side effect on

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the liver from lipid lowering and diabetic therapies. This cassette product has completed the feasibility phase and is starting the development process.

Cassette Products in Feasibility Studies

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

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.

High Sensitivity C-Reactive Protein. The high sensitivity C-Reactive Protein (CRP) test measures, by immunoassay, the amount of CRP present in a patient sample. CRP is an independent risk factor for coronary heart disease and is useful in predicting the risk of future cardiovascular events.

Direct Low Density Lipoproteins. The direct low density lipoproteins (LDL) cholesterol test permits the direct measurement of LDL cholesterol in a patient sample. The calculated LDL cholesterol is subject to a number of limitations including the need for a fasting sample. We expect the direct LDL cholesterol test to be reimbursable, whereas the calculated test is not.

WellCheck

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

Market Opportunity for Sponsors and Partnerships

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

Many product and service companies are interested in reaching consumers who may potentially be at risk for elevated cholesterol and therefore more likely to purchase their products. Because our technology and services provide an interactive channel to consumers, we believe we are also an attractive partner to companies such as insurance companies and the manufacturers of food, vitamins and other non-regulated nutraceutical products that have features and benefits designed to reduce cholesterol.

The increase of self-insured employers and the increase of corporate wellness programs offered by employers are also fostering a demand for our products and services. We are well positioned to help these

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companies provide programs to screen employees for cardiovascular risk and support cardiovascular health programs within each employer s healthcare plan.

We believe we are well positioned to meet the needs of potential sponsors and partners. We plan to continue to establish and maintain relationships with potential third-party sponsors and partners. Our unique technology and easy and convenient services provide access to target markets, creating unique opportunities for our customers.

Overview of WellCheck Testing Services

WellCheck uses the LDX System to provide health screenings for leading pharmaceutical, consumer product and corporate wellness clients throughout the nation at convenient consumer venues. WellCheck s professionals provide high quality services and offer test event expertise to both event sponsors and consumers. As part of our testing services, we utilize our proprietary TEAMS technology which automates registration, data acquisition and information management at promotional, corporate wellness and other consumer testing events and provides consumers with a personalized risk assessment for heart disease. A large portion of WellCheck s revenue has been derived from promotional programs with major pharmaceutical companies marketing lipid-lowering statin drugs. We believe an opportunity exists to further expand our testing services business in the promotional, corporate wellness and other convenient venues which broaden consumer access to testing while assisting pharmaceutical and consumer product companies in customer acquisition. Our goal is to expand our testing services, thereby increasing sales of test cassettes manufactured by our Diagnostic Products business.

We intend to seek opportunities to expand our WellCheck business through both internal development of new customer relationships and the assessment of additional acquisition or partnership candidates to add more specific regional coverage to WellCheck s testing services.

In addition, we continue to augment and further develop the capabilities of our TEAMS software, a proprietary interactive testing program designed to facilitate the operation of a cholesterol-related disease testing event using the LDX System. TEAMS is used to capture participants registration, self health assessment and results from the LDX System while supporting event logistic processes. Information is processed following NCEP guidelines. Individual participant reports, created for one-to-one education and consulting with a WellCheck health promotion associate to assess an individual s results and potential risk of heart disease based on the long-established Framingham Study, can be provided immediately at the test site. During the next fiscal year, we intend to broaden the number of diagnostic devices that will be able to interact with our TEAMS software.

Strategic Relationships

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

Abbott Laboratories

We signed an agreement with Abbott Laboratories to conduct screenings for high cholesterol and metabolic syndrome at selected healthcare industry conventions in 2002. In conjunction with this agreement,

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WellCheck will offer a special screening program designed to educate healthcare providers on the role that high cholesterol and metabolic syndrome play in cardiovascular disease.

Allegiance Healthcare Corporation

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

AstraZeneca Pharmaceuticals LP

We signed two agreements with AstraZeneca Pharmaceuticals LP (AstraZeneca) to provide cholesterol testing and information services as part of its employee outreach activities. One program took place in mid-2001 and the second program is scheduled to take place in mid-2002. Our Diagnostic Products business unit is in discussions with AstraZeneca to participate in its clinical trials for Crestor, a next generation statin developed by AstraZeneca, on both a domestic and international basis. We anticipate further involvement for our diagnostic product and testing services businesses with AstraZeneca upon the launch of Crestor.

Entertainment Marketing, Inc.

WellCheck has signed an agreement with Entertainment Marketing, Inc. (EMI), an event marketing company, to provide cholesterol testing services for Viagra® at venues including Major League Baseball events, multicultural health fairs and retail establishments. In the past, WellCheck has provided testing at EMI-sponsored events such as concerts.

McKesson Corporation

We have a long-term distribution partnership with McKesson Corporation (McKesson), a leading healthcare supply management company in North America. Through this partnership, we have access to the 500 sales professionals of McKesson s primary care division who call on over 100,000 physician offices and clinics in the United States of America.

Moore Medical Corp.

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

Physician Sales and Service, Inc.

We entered into a distribution partnership with Physician Sales and Service Inc. in 1996 for the distribution of our diagnostic products to physician offices. Physician Sales and Service has been our largest single customer for the last three years, contributing revenue of $8.6 million in fiscal 2002, $6.1 million in fiscal 2001 and $4.6 million in fiscal 2000.

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Pfizer Inc.

Our LDX System continues to be utilized in a number of regionally based marketing programs in the United States of America for Pfizer Inc. (Pfizer) in connection with Pfizer s products, as well as field based clinical trials for Lipitor®. Our international sales and marketing team continues to work with Pfizer throughout Europe in connection with physician office and corporate wellness focused marketing programs. Pfizer has renewed its agreement with WellCheck to provide cholesterol testing services at selected healthcare industry conventions in 2002.

Sankyo Pharma Inc.

We signed two agreements with Sankyo Pharma Inc. (Sankyo), the independent United States of America subsidiary of Tokyo-based Sankyo Co. Ltd., to provide cholesterol testing and information services in 2002. WellCheck will provide cholesterol testing and information services for Sankyo at selected healthcare industry professional conventions. In addition, WellCheck will provide cholesterol testing and information services at Sankyo-sponsored pilot programs administered at regional educational symposia for the Preventive Cardiovascular Nurses Association in connection with Sankyo s community outreach activities to increase awareness regarding heart disease and encourage lifestyle changes that promote better health.

WellCall Inc.

We entered into a non-exclusive distribution agreement with WellCall Inc. (WellCall), a nationwide provider of preventive health, education, coaching and complementary care referral services, to provide cholesterol testing services to its employer and health plan clients. Through this agreement, WellCheck s testing services are marketed by WellCall to over 400,000 members. We believe this agreement will expand WellCheck s presence in the corporate health and wellness market.

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 and consumer product segments. In order to fulfill this strategy and create opportunities for our products and services, we intend to expand our professional salesforce and focus our efforts on partnering, distribution and marketing activities.

Diagnostic Products

The sales and marketing strategy for our Diagnostic Products business is to increase penetration into the physician office laboratory and health promotion markets and leverage our installed base of LDX Analyzers. We are expanding our domestic and international sales associates as well as our distribution network and plan to dedicate a significant portion of the sales and marketing efforts of our Diagnostic Products business to educate current and potential owners of LDX Systems about the clinical and economic benefits of diagnostic screening and therapeutic monitoring with the LDX System and about new test cassettes as they become available for distribution. We also plan to continue to cultivate strategic relationships with development partners, pharmaceutical companies and distributors. We intend to leverage the technology, customer base, marketing power and distribution networks of these partners to accelerate

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market penetration and cassette usage. Diagnostic Products current marketing activities are primarily focused on:

Physician Office Laboratories. We have entered into nonexclusive distribution agreements with three national medical products distributors, Physician Sales and Service, Allegiance and McKesson, which together have more than 1,700 sales professionals who focus on the United States of America physician office laboratory market. We have retained more than 45 regional distributors in the United States of America. In addition, we and our distributors focus our sales and marketing efforts on physicians whose practices include a high incidence of the cholesterol-related diseases targeted by our test cassettes, including cardiologists, lipid clinicians, internists and family practitioners.

Health Promotion. We have ongoing relationships with approximately 15 regional distributors who provide equipment and supplies to customers that conduct diagnostic screening for cholesterol and related lipid levels and diabetes. Additionally, through agreements with regional distributors and screening organizations, we provide the LDX System for the diagnostic screening of employees of Exxon Corporation, General Motors Corporation, Ford Motor Company and Sears, Roebuck and Co. We have also entered into non-exclusive nationwide distribution agreements with Edwards Medical Supply and Moore Medical who specialize in the occupational health arena.

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

WellCheck

The sales and marketing strategy for our WellCheck business is to broaden the geographic coverage of WellCheck s testing services and further penetrate the promotional, corporate wellness and other consumer testing venue markets. We plan to continue to establish and maintain relationships with industry leaders in our target markets, particularly pharmaceutical companies, consumer product companies, corporate wellness partners and public health programs.

Competition

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

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offer broader product lines than us, have greater name recognition than us and offer discounts as a competitive tactic. In addition, several smaller companies are currently making or developing products that compete or will compete with ours. We believe we currently have a competitive advantage due to the status of the LDX System as the only CLIA waived system capable of performing multiple tests simultaneously on a single instrument, the improving breadth of the CLIA waived tests that we offer, the installed base of our LDX product and our network of over 70 distributors. We expect that our competitors will compete actively to maintain and increase market share and will seek to develop multi-analyte tests that qualify for CLIA waiver.

Our WellCheck business is one of numerous preventive care testing services across the United States of America. Competing testing services companies are almost exclusively regional and privately held, with limited access to capital. In addition, we utilize our proprietary TEAMS technology which automates registration, data acquisition and information management at testing events, providing participants with a personalized risk assessment for heart disease. While we believe the market opportunity for nationwide consumer testing for cholesterol vastly exceeds the current ability of all existing testing services combined, there is no guarantee that a larger, more well-known company with greater access to capital than us may not choose to take advantage of this market opportunity by competing with us.

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

Manufacturing

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

LDX Analyzer. The LDX Analyzer incorporates a variety of subassemblies and components designed or specified by us, including an optical element, microprocessors, circuit boards, a liquid crystal display and other electrical components. These components and subassemblies are manufactured by a variety of third parties and are shipped to us for final assembly and quality assurance. Our manufacture of the LDX Analyzer consists primarily of assembly, testing, inspection and packaging. Testing consists of a burn-in period, functional tests and integrated system testing using specially produced test cassettes. Our manufacturing process meets FDA Quality System Requirements and ISO 9001 and United Laboratories Guidelines. We believe we can expand our current LDX Analyzer manufacturing capacity as needed.

Cassettes. We purchase chemicals, membranes, plastic parts and other raw materials from third party suppliers and convert these raw materials, using proprietary processes, into single-use test cassettes. We believe our proprietary processes and custom designed equipment are important components of our cassette manufacturing operations. We have developed core manufacturing technologies, processes and production machinery, including membrane lamina-

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tion 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 ISO guidelines, including in process and final quality assurance testing. We have two fully operational cassette manufacturing lines and have recently installed our third manufacturing line which we are currently scaling up to full production capability.

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

Patents and Proprietary Technology

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

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

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

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

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

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

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

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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. The State of California also regulates and inspects our manufacturing facilities. We have been inspected twice by the State of California to date and are manufacturing under an issued medical device manufacturer s facility license from the State of California. If any violations of our applicable regulations are noted during a FDA, European Notified Body or State of California inspection of our manufacturing facilities or those of our contract manufacturers, the continued marketing of our products could be materially adversely affected.

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

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

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

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Clinical Laboratory Improvement Act Regulations

The use of our products in the United States of America 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 of America, healthcare providers, such as hospitals and physicians, that purchase products such as the LDX System and single-use test cassettes generally rely on third party payors, including private health insurance plans, federal Medicare, state Medicaid and managed care organizations, to reimburse all or part of the cost of the procedure in which the product is being used. Our ability to commercialize our products successfully in the United States of America will depend in part on the extent to which reimbursement for the costs of tests performed with the LDX System and related treatment will be available from government health authorities, private health insurers and other third party payors. Third party payors can affect the pricing or the relative attractiveness of our products by regulating the maximum amount of reimbursement provided by such payors for testing services. Reimbursement is currently not available for certain uses of our products in particular circumstances. For example, tests performed in the health promotion market are generally not subject to reimbursement. Pharmacists also face blocking state legislation in a number of states, which precludes them from accessing federally available reimbursement codes and practices. Third party payors are increasingly scrutinizing and challenging the prices charged for medical products and services. Decreases in reimbursement amounts for tests performed using our products may decrease amounts physicians and other practitioners are able to charge patients, which in turn may adversely affect our ability to sell our products on a profitable basis. In addition, certain healthcare providers are moving toward a managed care system in which such providers contract to provide comprehensive healthcare for a fixed cost per patient. Managed care providers are attempting to control the cost of healthcare by authorizing fewer elective procedures, such as the screening of blood for chronic diseases. We are unable to predict what changes will be made in the reimbursement methods used by third party payors. The inability of healthcare providers to obtain reimbursement from third party payors, or changes in third party payors policies toward reimbursement of tests using our products, could have a material adverse effect on our business, financial condition and results of operations. Given the efforts to control and reduce healthcare costs in the United States of America 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. (This organization was recently renamed the Centers for Medicare &

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Medicaid Services (CMS).) Under this system of reimbursement, equipment costs generally are not reimbursed separately, but rather are included in a single, fixed rate, per patient reimbursement. Medicare reform legislation requires CMS to implement a prospective payment system for outpatient hospital services as well. This system may also provide for a per-patient fixed rate reimbursement for outpatient department capital costs. We believe these regulations place more pressure on hospitals operating margins, causing them to limit capital expenditures. These regulations could have an adverse effect on us if hospitals decide to defer obtaining medical equipment as a result of any such limitation on their capital expenditures. The Medicare legislation also requires CMS to adopt uniform coverage and administration policies for laboratory tests. We are unable to predict what adverse impact on us, if any, additional government regulations, legislation or initiatives or changes by other payors affecting reimbursement or other matters that may influence decisions to obtain medical equipment may have.

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

Product Liability and Insurance

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

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

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

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

Employees

As of March 29, 2002, we employed 220 full-time associates, including 155 in our Diagnostic Products business, 49 in our WellCheck business and 16 in corporate administration. In addition to the 49 full-time associates in our WellCheck business, we also employed 16 part-time associates in that business. There were 96 employees in sales, marketing and administration, 81 employees in manufacturing, 41 employees in field testing (including the 16 part-time employees) and 18 employees devoted to research and development. None of our associates are covered by a collective bargaining agreement, and management considers relations with employees to be excellent.

Executive Officers

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

Name	Age	Position
Warren E. Pinckert II	58	President, Chief Executive Officer and Director
William W. Burke	43	Vice President of Finance, Chief Financial Officer, Treasurer and Secretary
Thomas M. Chauvin	47	Vice President of WellCheck
Robert J. Dominici	58	Executive Vice President and Chief Operating Officer
David A. Gyorke	42	Vice President of Operations
Timothy I. Still	36	Vice President of Sales and Marketing
Kevin R. Stromberg	40	Chief Information Officer
Terry L. Wassmann	55	Vice President of Human Resources
Thomas E. Worthy	60	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

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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.

Thomas M. Chauvin has served as our Vice President of WellCheck since September 2001. From January 2000 to May 2001, he served as the Vice President of Sales and Marketing for our WellCheck business. From February 1988 to January 2000, Mr. Chauvin was President and Chief Executive Officer of Health Net, Inc., the national wellness and health promotion company we acquired in January 2000. Prior to founding Health Net, Inc., Mr. Chauvin served in various executive management roles in the marketing and advertising industry.

Robert J. Dominici has served as our Chief Operating Officer since June 2001. In September 1999, Mr. Dominici was appointed to Chief Operating Officer of our Diagnostic Products business. He joined our company as Executive Vice President of Marketing and Sales in August 1998. From January 1997 to May 1998, Mr. Dominici served as Senior Vice President/ General Manager Corporate Accounts for Boehringer Mannheim Corporation, a healthcare diagnostic products company. Previously, Mr. Dominici held positions within Boehringer Mannheim including Vice President Marketing, Sales and Services and President of the Laboratory Systems Division. From February 1992 to December 1997, he was President and Chief Executive Officer of Microgenics Corporation, a wholly owned subsidiary of Boehringer Mannheim. Mr. Dominici holds a Bachelor of Science degree in Biology and Chemistry from Otterbein College.

David A. Gyorke has served as our Vice President of Operations since June 2000. From January 1999 to June 2000, Mr. Gyorke served as our Director of the Operations Engineering Groups. From November 1993 to January 1999, Mr. Gyorke was the Manufacturing & Technology Engineering Manager of Target Therapeutics, a neuro medical device manufacturer and a division of the Boston Scientific Corporation. Mr. Gyorke has also held positions with Bio-Rad Laboratories, Diasonics Ultrasound Inc. and defense contractors ArgoSystems, Inc. and Raytheon Company. Mr. Gyorke holds a Bachelor of Science degree in Industrial Engineering from the California Polytechnic State University, San Luis Obispo.

Timothy I. Still has served as our Vice President of Marketing and Sales since January 2002. From December 1997 to January 2002, Mr. Still served as the Vice President of Marketing and Sales of our Diagnostic Products business. From August 1992 to November 1997, Mr. Still was a Director of Global Marketing and Business Development for Boehringer Mannheim Corporation. Before joining Boehringer Mannheim, Mr. Still was a Product Manager with Bio-Rad Laboratories. Mr. Still holds a Bachelor of Science degree in Biological Sciences from the University of California at Davis and a Masters of Business Administration degree in Marketing and Entrepreneurship from the University of Southern California.

Kevin R. Stromberg has served as our Chief Information Officer since November 2001. From January 2001 to November 2001, he was the Vice President of Engineering and Operations for our WellCheck business. Mr. Stromberg served as the Vice President of Engineering of WellCheck.com from April 2000 to January 2001. From February 1998 to April 2000, he was Director of Information Technology for Bay Alarm Company. From January 1996 to February 1998, Mr. Stromberg held the position of Engineering Manager for Sun Microsystems, Inc. From 1994 to 1996, he held several positions at Shared Medical Systems Allegra Division. Additionally, he has held positions with Interactive Development Environments, Inc. and Wollongong Software and operated his own consulting business. Mr. Stromberg holds a Bachelor of Science degree in Computer Information Systems from the University of San Francisco.

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Terry L. Wassmann has served as our Vice President of Human Resources since March 2000. Before joining Cholestech, Ms. Wassmann served as Staff Relations Manager with Robert Half International from July 1999 to March 2000. From February 1986 to December 1999, Ms. Wassmann was employed by Boehringer Mannheim where she held numerous positions within the Human Resources department, including the Director of Human Resources of the Indiana and California based Diagnostics Division. Ms. Wassmann has been awarded the SPHR title from the Society of Human Resource Management.

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

ITEM 2: PROPERTIES

We lease 47,000 square feet in Hayward, California and 5,100 square feet in Oakland, California. Our facilities contain approximately 8,000 square feet of laboratory space and 10,000 square feet of manufacturing space with the balance devoted to marketing and administrative and common areas. Our original lease and renewals for the Hayward facility expired on March 31, 2002. We have negotiated a new lease for five years for this location starting on April 1, 2002 with an option to extend the lease for an additional three-year term. On July 1, 2002 we will lease approximately 29,000 more square feet of the Hayward building which will allow us to eventually consolidate operations currently located in Oakland and at a second Hayward location. We also lease 3,000 square feet on a month-to-month basis in Hammond, Louisiana for our WellCheck business. We believe that our existing facilities are adequate for the present and that additional space will be available as needed.

ITEM 3: LEGAL PROCEEDINGS

On February 5, 1999, a complaint entitled Ree v. Pinckert, et al., No. C99-0562 (PJH) was filed in the United States District Court for the Northern District of California. The action was a class action and the complaint alleged that we and certain of our current and former officers violated the federal securities laws by making false and misleading statements concerning our company and its business during the period of June 28, 1996 through June 25, 1998. On June 14, 2001, we executed an agreement in principle with plaintiffs to resolve this matter for a payment of $3.0 million by our insurance carrier. We recorded a $1.3 million charge during the fiscal year ended March 30, 2001 for legal fees and insurance costs related to resolving this matter. We paid $855,000 to our insurance company and $121,000 for legal fees in the quarter ended June 29, 2001. The settlement received court approval on October 31, 2001.

On December 23, 1999, a complaint entitled Roche Diagnostics GmbH v. Health Care Solutions AG, Euredix N.V./SA and Cholestech Corporation was filed with the Canton Court of the Canton Zug in Zug, Switzerland by Roche Diagnostics seeking a cease and desist order barring us and two of our distributors from distributing HDL assay single-use test cassettes in Switzerland. The complaint alleges that we violated a Roche European patent for HDL. On July 11, 2000, the court denied the plaintiff 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 us and ordered the plaintiff to pay our legal fees.

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There can be no assurance as to whether the plaintiff will appeal this ruling or whether any additional action will be resolved in our favor. At this point in time no schedule has been set regarding additional court activity.

In January 2000, a complaint, No. 4 O 4/00, was filed in the District Court, Dusseldorf, Germany by Roche Diagnostics against us, and two of our distributors, seeking a cease and desist order barring the distributors from shipping HDL single-use test cassettes into Germany. The complaint alleges we, and our distributors, violated a Roche German priority patent for HDL by selling our single-use test cassette containing a HDL assay. On December 4, 2001, a hearing was held in Dusseldorf, Germany at which Cholestech and Roche witnesses testified. A hearing has been set for October 29, 2002. We believe the suit is without merit and intend to defend the case vigorously. However, there can be no assurance that the lawsuit will be resolved in our favor.

On August 2, 2000, we filed a complaint, No. 3 Ni 40/00, in Munich, Germany seeking nullification of the German patent for measurement of HDL cholesterol owned by Roche Diagnostics. On December 6, 2001, a hearing was held in Munich on the merits of the nullity complaint. The federal Patent 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, a complaint, No. Ei/Ti ROCH 04002 was filed in Vienna, Austria by Roche Diagnostics, seeking a cease and desist order barring us and one of our distributors from distributing HDL assay single-use test cassettes in Austria. The complaint alleges that we violated a Roche European patent for HDL. At this point, no schedule has been set regarding court activity. There can be no assurance as to whether the plaintiff will take any additional action or whether any additional action will be resolved in our favor.

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

None.

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PART II

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

Our common stock is quoted on the NASDAQ National Market under the symbol CTEC. On March 28, 2002, the last reported sale price for our common stock on the NASDAQ National Market was $17.87 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 2001		
First Quarter	$ 8.97	$ 6.00
Second Quarter	8.00	6.38
Third Quarter	7.50	4.81
Fourth Quarter	6.59	3.69
Fiscal Year 2002		
First Quarter	$ 8.75	$ 4.06
Second Quarter	17.90	7.57
Third Quarter	27.60	14.40
Fourth Quarter	22.00	10.82

As of May 31, 2002 there were 13,382,498 shares of our common stock issued and outstanding and held by approximately 173 holders of record.

Dividend Policy

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

ITEM 6: SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated financial data should be read in conjunction with our consolidated financial statements and notes thereto and Management s Discussion and Analysis of Financial Condition and Results of Operations. The following selected consolidated statement of operations data for the fiscal years ended March 29, 2002, March 30, 2001 and March 31, 2000 and the selected consolidated balance sheet data as of March 29, 2002 and March 30, 2001 are derived from, and qualified by reference to, the audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. The selected consolidated statement of operations data for the fiscal years ended March 26, 1999 and March 27, 1998 and the consolidated balance sheet data as of March 31, 2000, March 26, 1999 and March 27, 1998 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.

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	Year Ended March 31,(1)				
	2002	2001	2000	1999	1998
	(in thousands, except per share data)				
Consolidated Statement of Operations Data:					
Revenue	$47,366	$37,003	$27,549	$22,032	$21,664
Cost of revenue(2)	19,009	15,906	11,211	10,252	10,513
Gross profit	28,357	21,097	16,338	11,780	11,151
Operating expenses:					
Sales and marketing	13,836	11,388	7,032	6,606	5,380
Research and development	2,564	2,586	3,021	2,703	2,224
General and administrative	6,375	5,079	3,510	2,381	2,087
Website and other related costs(2)	246	1,326			
Goodwill amortization		709	100		
Legal and other related		1,312	219	826	
Impairment charge		1,958			
Total operating expenses	23,021	24,358	13,882	12,516	9,691
Income (loss) from operations	5,336	(3,261)	2,456	(736)	1,460
Interest and other income, net	449	655	805	663	569
Income (loss) before taxes	5,785	(2,606)	3,261	(73)	2,029
Provision for income taxes	235		129		41
Net income (loss)	$ 5,550	$ (2,606)	$ 3,132	$ (73)	$ 1,988
Net income (loss) per share:					
Basic	$ 0.44	$ (0.22)	$ 0.27	$ (0.01)	$ 0.18
Diluted	$ 0.40	$ (0.22)	$ 0.26	$ (0.01)	$ 0.17
Shares used to compute net income (loss) per share(3):					
Basic	12,658	12,046	11,724	11,484	11,289
Diluted	13,730	12,046	11,920	11,484	11,905

	Year Ended March 31,(1)				
	2002	2001	2000	1999	1998
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and marketable securities	$ 22,107	$ 12,365	$ 13,741	$ 11,427	$ 14,751
Working capital	20,848	10,254	11,522	13,342	17,662
Total assets	42,751	30,742	32,218	24,283	25,788
Accumulated deficit	(42,480)	(48,030)	(45,424)	(48,556)	(48,483)
Shareholders equity	36,721	24,858	26,476	21,769	21,446

(1) Our fiscal year is a 52 - 53 week period ending on the last Friday in March. All fiscal years referenced in this Annual Report on Form 10-K consisted of 52 weeks, except fiscal 2000, which consisted of 53 weeks. For convenience, we have indicated in this Annual Report on Form 10-K that our fiscal year ends on March 31 and refer to the fiscal year ending March 29, 2002 as fiscal 2002, the fiscal year ending March 30, 2001 as fiscal 2001, the fiscal year ending March 31, 2000 as fiscal 2000, the fiscal year ending March 26, 1999 as fiscal 1999 and the fiscal year ending March 27, 1998 as fiscal 1998.

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(2) Cost of revenue and website and other related costs have been revised as a result of reclassification of certain costs into costs of revenue and out of website and other related costs relating to our TEAMS software.

(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 RESULTS OF OPERATIONS AND FINANCIAL CONDITION

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

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

Overview

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

Diagnostic Products develops, manufactures and markets our Cholestech LDX® System (the LDX System) which performs alternate site diagnostic testing to assist in assessing for risk of heart disease, diabetes and certain liver diseases and in the monitoring of therapy to treat those diseases.

WellCheck conducts consumer testing within the United States of America that assesses the risk of heart disease and other diseases and assists in the monitoring of therapy to treat those diseases. Through its Test Event Activity Management Software (TEAMS), WellCheck collects test results and other patient data (in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and aggregates that data for testing event sponsors use in marketing programs.

In fiscal 2001, we engaged in a third business segment, WellCheck.com, our interactive internet site. The Company determined that starting in fiscal 2002, WellCheck and WellCheck.com would be operated and managed as one segment. All operating results present the combined results for WellCheck and WellCheck.com as a single segment, and as a result, all prior year activity has been combined to reflect this change.

Diagnostic Products currently manufactures and markets the LDX System, including the LDX Analyzer and a variety of single-use test cassettes, in the United States of America, Europe, Asia and South America. The LDX System 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

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blood cholesterol, related lipids, glucose and liver enzymes, and are used to test patients at risk of or suffering from heart disease, diabetes and liver disease.

WellCheck, funded by third-party sponsors, uses the LDX System to provide health screenings for leading pharmaceutical, consumer product and corporate wellness clients throughout the nation in convenient consumer venues. These testing service activities result in additional sales of test cassettes manufactured by our Diagnostic Products business. WellCheck s professionals provide high quality services and offer test event expertise to both event sponsors and consumers. As part of our testing services, we utilize our proprietary TEAMS technology which automates registration, data acquisition and information management at promotional, corporate wellness and other consumer testing events and provides consumers with a personalized risk assessment for heart disease. WellCheck has developed its technology with the input from a variety of authorities on health information privacy practices. TEAMS incorporates procedures that meet state and federal legislation, such as HIPAA, concerning the use of protected health information.

Substantially all of WellCheck s revenue is derived from promotional programs with major pharmaceutical companies marketing lipid-lowering statin drugs. We believe an opportunity exists to further expand our testing services business in the promotional, corporate wellness and other convenient venues which broaden consumer access to testing while assisting consumer product companies, such as pharmaceutical companies, in customer acquisition. Our goal is to expand our testing services, thereby increasing sales of test cassettes manufactured by our Diagnostic Products business.

Our ongoing investment relating to WellCheck may result in continuing negative cash flows for this recently acquired business unit. We intend to continue to make significant expenditures in sales, marketing, development and TEAMS to develop this business. The amount and timing of expenditures will have an impact on our ability to maintain profitability and positive cash flows.

As WellCheck s third party sponsorships evolve, the number of testing events and tests performed will vary and revenue will fluctuate. In an effort to diversify our customer base, we have established relationships with various third party sponsors for the upcoming fiscal year, but the exact timing and level of these sponsorships have not yet been finalized. Additionally, WellCheck s revenue will be influenced by seasonality. During the last two months of the calendar year, promotional testing decreases significantly as sponsors budgets become fully spent. In addition, people typically pursue other interests and are less focused on chronic health issues during this time period.

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Results of Operations

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

	Fiscal Year Ended		
	March 29, 2002	March 30, 2001	March 31, 2000
Revenue			
Product	88%	88%	98%
Service	12	12	2
Total	100	100	100
Cost of revenue			
Product	36	38	40
Service	4	5	1
Total	40	43	41
Gross profit	60	57	59
Operating expenses			
Sales and marketing	29	31	25
Research and development	5	7	11
General and administrative	14	14	13
Web site and other related costs	1	4	
Goodwill amortization		2	
Legal and other related		3	1
Impairment charge		5	
Total operating expenses	49	66	50
Income (loss) from operations	11	(9)	9
Interest and other income	1	2	3
Provision for income taxes			1
Net income (loss)	12%	(7)%	11%

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

Revenue. Our total revenue increased 28% to $47.4 million in fiscal 2002 from $37.0 million in fiscal 2001. Diagnostic Products represented 88% of total revenue in both fiscal 2002 and fiscal 2001.

International revenue represented 17% of our total revenue in both fiscal 2002 and fiscal 2001. In fiscal 2002 and 2001 all international revenue related to Diagnostic Products.

Segment performance was as follows:

Diagnostic Products revenue increased 28% to $41.7 million in fiscal 2002 from $32.5 million in fiscal 2001. The increase in revenue primarily reflected a 29% increase in unit sales of single-use test cassettes across all market segments. Additionally, unit sales of the LDX System increased 17%.

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WellCheck revenue, inclusive of reimbursements related to travel, increased 23% to $7.2 million, before inter-company eliminations, in fiscal 2002 from $5.9 million in fiscal 2001. The increase in revenue reflected a large contract from a single customer, which was completed in December 2001. The contract was not renewed, however we have signed agreements with several new customers as part of our ongoing efforts to diversify our WellCheck customer base.

Cost of Revenue. Our cost of revenue increased 20% to $19.0 million in fiscal 2002 from $15.9 million in fiscal 2001. Gross margins were 60% in fiscal 2002 and 57% in fiscal 2001. Diagnostic Products accounted for 90% of our cost of products sold and the other 10% related to WellCheck service revenue in fiscal 2002. Diagnostic Products accounted for 88% of our costs of products sold and 12% related to service revenue in fiscal 2001.

Segment performance was as follows:

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

We have licensed certain technology used in some of our products. The license agreement, which expires in 2006, requires us to pay a royalty of 2.0% on net sales of single use test cassettes. Total royalty expense was $755,000 in fiscal 2002 and $490,000 in fiscal 2001 and was included in the cost of product revenue.

WellCheck cost of revenue includes reimbursed travel expenses, laboratory services, maintenance of TEAMS software, medical waste disposal and the cost of medical testing equipment, cassettes and supplies. Costs of product provided by the Diagnostic Products business are eliminated on consolidation. Total cost of revenue increased 6% to $2.0 million in fiscal 2002 from $1.9 million in fiscal 2001. The increase was related to the higher volume of testing performed during the year. This was offset by travel costs which were significantly lower than last year, due to a single contract where the customer directly paid for airfare and other transportation costs. Gross margin was 51% in fiscal 2002 before inter-company eliminations compared to 45% in fiscal 2001 before inter-company eliminations.

Operating Expenses

Sales and Marketing. Our sales and marketing expenses include salaries, commissions, bonuses, expenses for outside services related to marketing programs and travel expenses. Sales and marketing expenses increased 22% to $13.8 million in fiscal 2002 from $11.4 million in fiscal 2001. Sales and marketing expenses decreased to 29% of revenue in fiscal 2002 from 31% of revenue in fiscal 2001. Diagnostic Products accounted for 72% of sales and marketing expenses in fiscal 2002 and 69% of sales and marketing expenses for fiscal 2001. WellCheck represented 27% of sales and marketing expenses in both fiscal years. Unallocated corporate sales and marketing expenses were 1% of total sales and marketing expense in fiscal 2002 compared to 4% in fiscal 2001. This decrease was due to a reduction in the use of outside services, primarily public relations.

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Sales and marketing expenses in each of our segments were as follows:

Diagnostic Products sales and marketing expenses increased 28% to $10.0 million in fiscal 2002 from $7.8 million in fiscal 2001. The increase was related to increased wages and other related costs resulting from increased staffing. Sales and marketing expenses remained at 24% of revenue in both fiscal 2002 and fiscal 2001.

WellCheck sales and marketing expenses increased 20% to $3.7 million in fiscal 2002 from $3.1 in fiscal 2001. The increase was primarily related to increased staffing of testers to support higher testing volume. Sales and marketing expenses declined to 52% of revenue in fiscal 2002 from 53% in fiscal 2001.

Research and Development. Our research and development expenses include salaries, bonuses, expenses for outside services, supplies and amortization of capital equipment. Research and development expenses remained constant at $2.6 million in fiscal 2002 and fiscal 2001. Research and development expenses as a percentage of revenue decreased to 5% in fiscal 2002 compared to 7% in fiscal 2001. Diagnostic Products accounted for 100% of research and development expenses in fiscal 2002 and 85% of research and development expenses in fiscal 2001. WellCheck incurred 15% of the research and development expenses in fiscal 2001.

Research and development expenses in each of our segments were as follows:

Diagnostic Products research and development expenses increased 17% to $2.6 million in fiscal 2002 from $2.2 million in fiscal 2001. This increase was primarily attributable to wage and other costs related to an increase in the number of associates as we began immunoassay test development. Research and development expenses as a percentage of revenue decreased to 6% in fiscal 2002 compared to 7% in fiscal 2001.

WellCheck research and development expenses were $392,000 in fiscal 2001 and were related to certain costs incurred in the development of our website and TEAMS software.

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 26% to $6.4 million in fiscal 2002 from $5.1 million in fiscal 2001. General and administrative expenses were maintained at 14% of revenue in both fiscal 2002 and fiscal 2001. Unallocated corporate expenses were 71% of total general and administrative expenses in fiscal 2002 and 69% in fiscal 2001. Diagnostic Products represented 13% of general and administrative expenses in fiscal 2002 and 16% of general and administrative expenses in fiscal 2001. WellCheck accounted for 16% of general and administrative expenses in fiscal 2002 and 15% of general and administrative expenses in fiscal 2001.

General and administrative expenses in each of our segments were as follows:

Diagnostic Products general and administrative expenses increased 4% or $28,000 to $823,000 in fiscal 2002 from $795,000 in fiscal 2001. General and administrative expenses stayed constant at 2% of revenue in fiscal 2002 and in fiscal 2001.

WellCheck general and administrative expenses were $1.0 million in fiscal 2002 compared to $787,000 in fiscal 2001. In fiscal 2002 general and administrative expenses were 14% of revenue

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representing a small increase from 13% of revenue in fiscal 2001. Increased staffing resulted in higher costs for wages and other related costs.

Unallocated corporate general and administrative expenses were $4.5 million in fiscal 2002 compared to $3.5 million in fiscal 2001. The increase was related to severance expense for our former chief financial officer, increased wages and other costs related to an increase in the number of associates and higher insurance premiums.

Website and Related costs. Our website and related costs include expenses related to web hosting and related outside services. Website and related costs decreased 81% to $246,000 in fiscal 2002 from $1.3 million in fiscal 2001. Website and related costs decreased to 1% of revenue in fiscal 2002 from 4% in fiscal 2001. All costs were attributed to WellCheck for both fiscal 2002 and 2001. The decline in expenses related to the elimination of amortization of the website in fiscal 2001, as the cost of the website was written off at the end of fiscal 2001.

Goodwill Amortization. As the result of our adoption of SFAS No. 142 as of April 1, 2001, we recorded no goodwill amortization in fiscal 2002. Goodwill amortization expenses of $709,000 in fiscal 2001 included the amortization of capitalized costs associated with the purchase of Health Net, Inc. in January 2001. All costs were associated with our WellCheck business.

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

Impairment Charge. We recorded no impairment charge in fiscal 2002. In the fourth quarter of fiscal 2001 we recorded an impairment charge of $2.0 million relating to certain capitalized website costs as we no longer expected future cash flows from the website to be sufficient to recover the capitalized development costs.

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

Income Taxes. We have significant net operating loss (NOLs) and tax credit carryforwards. We recorded no provision for income taxes in fiscal 2001 due to the use of the net operating loss. The $235,000 provision for income taxes in fiscal 2002 represented the estimated state income taxes payable, reduced for the use of NOLs and tax credit carryforwards. Management expects to use NOLs and other tax carryforward amounts to the extent taxable income is earned in fiscal 2003 and beyond. As of March 29, 2002, we had NOL carryforwards of $37.4 million available to reduce future taxable income for federal income tax purposes; however, we have fully consumed our NOL carryforwards for California purposes. Additionally, we had research and development and other tax credit carryforwards available to reduce income taxes for federal income tax purposes of $2.0 million and research and development and other tax credit carryforwards available to reduce income taxes for state income tax purposes of $400,000. We have historically experienced significant operating losses and operate in an industry subject to rapid technological changes. Therefore, we believe there is sufficient uncertainty regarding our ability to generate future taxable income and use these NOLs and tax credit carryforwards such that a full valuation allowance for deferred tax assets was required at March 29, 2002. Over the course of the next year, we will review our position on our

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valuation allowance. If we continue to remain profitable during the coming fiscal year, there is a possibility that we will release our valuation allowance. Prior to the release of the valuation allowance, to the extent that we are profitable, our effective tax rate should continue to be substantially less than the applicable statutory rates. Following the release of our valuation allowance, our effective tax rate will approximate the applicable statutory rates.

As a result of a change in ownership (for tax purposes) which occurred in fiscal 1991, there is an annual limitation of approximately $1.5 million for federal and state income tax purposes on the combined use of approximately $6.1 million of federal net operating loss carryforwards and the use of approximately $550,000 of federal and state tax credit carryforwards.

Comparison of Fiscal Years Ended March 30, 2001 and March 31, 2000

Revenue. Our total revenue increased 34% to $37.0 million in fiscal 2001 from $27.5 million in fiscal 2000. Diagnostic Products represented 88% of total revenue in fiscal 2001 and 98% of total revenue in fiscal 2000.

International revenue represented 17% of total revenue in fiscal 2001 compared to 18% of total revenue in fiscal 2000. All international revenue related to Diagnostic Products.

Segment performance was as follows:

Diagnostic Products revenue increased 20% to $32.5 million in fiscal 2001 from $27.0 million in fiscal 2000. The increase in revenue primarily reflected an 18% increase in unit sales of single-use test cassettes. The growth was in the physician office laboratory, health promotion and international markets. Additionally, unit sales of the LDX System increased 43%. LDX sales increased in all markets, other than pharmacy.

WellCheck revenue, including revenue for WellCheck.com, increased significantly to $5.9 million, before inter-company eliminations, in fiscal 2001 from $743,000, before inter-company eliminations, in fiscal 2000. The increase in revenue reflected the fact that WellCheck was only included in our results of operations during the last two months of fiscal 2000.

Cost of Revenue. Our cost of revenue increased 42% to $15.9 million in fiscal 2001 from $11.2 million in fiscal 2000. Gross margins were 57% in fiscal 2001 and 59% in fiscal 2000. Diagnostic Products accounted for 88% of our cost of products sold and WellCheck and WellCheck.com accounted for 12% of our cost of products sold in fiscal 2001. Diagnostic Products accounted for 99% of our cost of products sold and WellCheck accounted for 1% of our cost of products sold in fiscal 2000.

Segment performance was as follows:

Diagnostic Products cost of revenue includes direct labor, direct material, overhead and royalties. Cost of revenue increased 27% to $14.1 million in fiscal 2001 from $11.1 million in fiscal 2000. The increase was primarily related to higher unit sales of single-use test cassettes and costs of validations and tests of our new manufacturing line for cassettes in connection with preproduction validation. Gross margin was 57% in fiscal 2001 and 59% in fiscal 2000. The gross margin decline was primarily attributable to spending related to prepare the new production equipment for full operation.

We have licensed certain technology used in the manufacturing of certain of our products. A related agreement, which expires in 2006, requires us to pay a royalty of 2% on net sales of

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single use test cassettes. Total royalty expense was $490,000 in fiscal 2001 and $456,000 in fiscal 2000 and such amounts were charged to cost of product revenue.

WellCheck cost of revenue, including cost of revenue for WellCheck.com, includes reimbursed travel expenses, laboratory services, medical waste disposal and the cost of medical testing equipment and supplies as well as costs related to TEAMS software support. Costs of product provided by Diagnostic Products are eliminated on consolidation. Total cost of revenue, before inter-company eliminations, was $3.2 million in fiscal 2001 and $349,000 for the two months of operations in fiscal 2000.

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 62% to $11.4 million in fiscal 2001 from $7.0 million in fiscal 2000. Sales and marketing expenses increased to 31% of revenue in fiscal 2001 from 25% of revenue in fiscal 2000. Diagnostic Products accounted for 69% of sales and marketing expenses for fiscal 2001 and 97% of sales and marketing expenses for fiscal 2000.

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

Diagnostic Products sales and marketing expenses increased 14% to $7.8 million in fiscal 2001 from $6.8 million in fiscal 2000. The increase relates to increased advertising, trade show and promotional costs. Sales and marketing expense decreased to 24% of revenue in fiscal 2001 from 25% of revenue in fiscal 2000.

WellCheck sales and marketing expenses increased significantly to $3.1 million in fiscal 2001 from $200,000 in fiscal 2000. This increase reflects the fact that WellCheck was only included in our results of operations for the last two months of fiscal 2000.

Corporate sales and marketing expenses were $477,000 in fiscal 2001, primarily for outside services such as public relations. We recorded no corporate sales and marketing expenses in fiscal 2000.

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 decreased 14% to $2.6 million in fiscal 2001 from $3.0 million in fiscal 2000. Research and development expenses, as a percentage of revenue, decreased to 7% in fiscal 2001 compared to 11% in fiscal 2000. Diagnostic Products accounted for 85% of research and development expenses in fiscal 2001 and 80% of research and development expenses in fiscal 2000. WellCheck incurred 15% of the research and development expenses in fiscal 2001.

Research and development expenses in each of our segments were as follows:

Diagnostic Products research and development expenses decreased 9% to $2.2 million in fiscal 2001 from $2.4 million in fiscal 2000. This decrease was primarily attributable to a reduction in the number of associates and expenses related to the development completion of the ALT single-use test cassette. Research and development expenses as a percentage of revenue decreased to 7% in fiscal 2001 compared to 9% in fiscal 2000.

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WellCheck research and development expenses were $392,000 in fiscal 2001 offset by $874,000 of certain capitalized website costs and $286,000 of capitalized TEAMS software development costs.

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, our medical advisory board and costs associated with our board of directors. General and administrative expenses increased 45% to $5.1 million in fiscal 2001 from $3.5 million in fiscal 2000. General and administrative expenses increased to 14% of revenue in fiscal 2001 from 13% in fiscal 2000. Diagnostic Products represented 16% of general and administrative expenses in fiscal 2001 and 7% of general and administrative expenses in fiscal 2000. WellCheck accounted for 15% of general and administrative expenses in fiscal 2001 and 11% of general and administrative expenses in fiscal 2000. Unallocated corporate expenses accounted for the remaining 69% of general and administrative expenses in fiscal 2001 and 82% of general and administrative expenses in fiscal 2000.

General and administrative expenses in each of our segments were as follows:

Diagnostic Products general and administrative expenses increased 202% to $795,000 in fiscal 2001 from $263,000 in fiscal 2000. General and administrative expenses decreased to 2% of revenue in fiscal 2001 compared to 1% in fiscal 2000. The increase relates to the wages, benefits and other costs for the segment s Chief Operating Officer and staff. This position was not created until the third quarter of fiscal 2000.

WellCheck general and administrative expenses were $787,000 in fiscal 2001 compared to $394,000 in fiscal 2000. The increase reflects that WellCheck was only included in our results of operations for the last two months of fiscal 2000, and WellCheck.com, now a part of WellCheck, had been included in our results of operations only for the last six months of fiscal 2000.

Unallocated corporate general and administrative expenses increased 23% to $3.5 million in fiscal 2001 from $2.9 million in fiscal 2000. The increase was attributed to wages and other costs relating to the addition of new associates, insurance and shared expenses for facilities, human resources and information services.

Goodwill Amortization. Goodwill amortization expense includes the amortization of capitalized costs associated with the purchase of Health Net in January 2000. Amortization expense increased 609% to $709,000 in fiscal 2001 from $100,000 in fiscal 2000. All costs were associated with the WellCheck business.

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

Impairment Charge. In the fourth quarter of fiscal 2001 we recorded an impairment charge of $2.0 million relating to certain capitalized website and database development costs as we no longer expected future cash flows from the website to be sufficient to recover the capitalized development costs. There was no impairment expense during fiscal 2000.

Interest and Other Income, Net. Interest income reflects income from the investment of cash balances and marketable securities, net of expenses. Interest income decreased 19% to $655,000 in fiscal

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2001 from $805,000 in fiscal 2000. This decrease was primarily the result of reduced cash equivalents and marketable securities resulting from investment in our WellCheck operations.

Liquidity and Capital Resources

We have financed our operations primarily through the sale of equity securities, including employee option exercises, and net cash provided by operations. From inception to March 29, 2002, we raised $79.2 million in net proceeds from equity financings. As of March 29, 2002, we had $22.1 million of cash, cash equivalents and marketable securities. In addition to these amounts, we have available an $8.0 million revolving bank line of credit agreement. While the agreement is in effect, we are required to deposit assets with a collective value, as defined in the line of credit agreement, equivalent to no less than 100% of the outstanding principal balance. Amounts outstanding under the line of credit bear interest at either our choice of 0.5% below the bank s prime rate or 1.75% above the LIBOR rate, depending on the payment schedule. The line of credit agreement expires on July 1, 2003. There were no borrowings under this line of credit during fiscal 2002, and as of March 29, 2002, there were no borrowings outstanding under the line of credit.

During fiscal 2002, we generated $6.0 million in cash from operating activities compared to $2.3 million in fiscal 2001. The cash provided during fiscal 2002 was composed primarily of a net income of $5.6 million and non-cash items including $2.6 million in depreciation and amortization, provision for doubtful accounts and returns of $105,000, inventory allowance of $30,000, a stock acceleration charge of $161,000 and increased accrued payroll and benefits of $1.2 million. This was partially offset by a $1.3 million increase in inventory, an $816,000 increase in accounts receivable, a $855,000 million legal payment, a $435,000 increase in prepaid expenses and a $224,000 decrease in accounts payable and accrued expenses. The cash generated from operations in fiscal 2001 was primarily due to cash consumed by a net loss of $2.6 million which was countered by non-cash items of $3.5 million in depreciation and amortization, impairment charges of $2.0 million, provision for doubtful accounts of $224,000 and inventory allowance of $107,000. Additionally, other favorable changes in working capital included accrued payroll and benefits of $337,000, a decrease in prepaid and other current assets of $167,000 and a $85,000 increase in accounts payable and accrued expenses. This was partially offset by a $1.4 million increase in accounts receivable and an increase in inventory of $51,000. The cash generated from operations in fiscal 2000 was primarily due to net income of $3.1 million, increases in accounts payable and accrued liabilities of $1.9 million, increases in accrued payroll and benefits of $573,000, reductions in accounts receivable and inventory totaling $1.4 million and depreciation and amortization of $1.6 million, partially offset by increased prepaid expenses of $756,000.

In fiscal 2002, we used $7.5 million of cash in investing activities through the net purchase of $5.1 million of marketable securities and the $2.4 million purchase of equipment. In fiscal 2001, net cash used in investing activities was $5.8 million and included the purchase of property and equipment of $4.2 million, the final Health Net purchase payment of $1.2 million and the net purchase of marketable securities of $1.4 million, which was partially offset by the recovery of $1.0 million of restricted cash. In fiscal 2000, net cash used by investing activities was $8.5 million, consisting primarily purchases of property and equipment of $4.2 million, the purchase of Health Net for $2.3 million, the creation of $1.0 million in restricted cash related to the final purchase price adjustment for the Health Net acquisition and the net purchase of marketable securities of $957,000.

Net cash provided by financing activities was $6.2 million in fiscal 2002 as compared to $560,000 for fiscal 2001 and $1.4 million for fiscal 2000. For all three years, cash provided by financing activities was

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primarily from the issuance of common stock pursuant to the employee stock purchase and employee stock incentive plans.

During fiscal 2003, we intend to invest approximately $2.4 million in capital purchases related to expansion of our information technology systems, expansion of our manufacturing capacity and research and development.

Future minimum payments due under lease obligations, including the new lease for our Hayward facility that commenced April 1, 2002, as of March 29 (in thousands):

Fiscal Year	Non Cancelable Operating Leases
2003	$1,118
2004	1,209
2005	1,223
2006	1,188
2007	1,115
Total	$5,853

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

Quarterly Financial Data

	Quarter Ended							
	Mar. 29, 2002	Dec. 28, 2001	Sept. 28, 2001	June 29, 2001	Mar. 30, 2001	Dec. 29, 2000	Sept. 29, 2000	June 30, 2000
	(In thousands, except share data) (unaudited)							
Revenue	$11,382	$11,467	$12,139	$12,378	$10,238	$8,849	$8,717	$9,199
Gross profit	6,695	6,578	7,696	7,388	5,682	4,880	5,064	5,471
Net income (loss)	$ 1,533	$ 1,154	$ 1,618	$ 1,245	$ (3,033)	$ (551)	$ 29	$ 949
Earnings (loss) per share:								
Basic	$ 0.12	$ 0.09	$ 0.13	$ 0.10	$ (0.25)	$ (0.05)	$ 0.00	$ 0.08
Diluted	$ 0.11	$ 0.08	$ 0.12	$ 0.10	$ (0.25)	$ (0.05)	$ 0.00	$ 0.08

Cost of revenue and website and other related costs have been revised as a result of the reclassification of certain website and other related costs as a component of cost of revenue relating to our TEAMS software. In the first quarter of fiscal 2002, the adjustment to cost of revenue was $227,000.

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Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. 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 on-going 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.

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

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

We state inventories at the lower of cost or market. We establish provisions for excess, obsolete and unusable inventories after evaluation of historical sales, forecasted sales, product expiration and current inventory levels. During fiscal 2002, $163,000 was charged to cost of revenue for excess, obsolete and unusable inventory. If the market value of our products decline, the demand for our products decline or if a significant amount of the material were to become unusable, our operating results could be adversely affected.

We maintain a warranty allowance for the estimated amount of repairs or replacement cost of all products which are found to be defective. Provisions for warranty are provided for in the same period that the related product sales are recorded. The amount of allowance is based upon analyses of historical repairs and replacements. Should the product defect rate increase, the need for additional allowance will increase and could adversely affect our results of operations.

We provide for income taxes based on estimated federal and state alternative minimum taxes payable, reduced for the use of NOLs and tax credit carryforwards. We have historically experienced significant operating losses and operate in an industry subject to rapid technological changes; therefore, we believe there is sufficient uncertainty regarding our ability to generate future taxable income and use these NOLs and tax credit carryforwards such that a full valuation allowance for deferred tax asset was required at March 29, 2002. Over the course of the next year, we will continue to review our position with respect to the necessity of the full valuation

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allowance. If we continue to remain profitable during the coming fiscal year and determine that realization of all or a portion of the NOLs is likely, then we may reduce or eliminate the valuation allowance. If the federal or state governments change the corporate income tax laws, our ability to use NOLs and tax credits could be reduced, adversely affecting our operating results.

We account for stock-based employee compensation arrangements in accordance with provisions of APB Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25) and comply with the disclosure provision of SFAS No. 123, *Accounting for Stock-based Compensation* (SFAS 123). The pro forma disclosure of the difference between compensation expense included in net income (loss) and the related cost measured by the fair value method is presented in Note 6 to the consolidated financial statements included in this Annual Report on Form 10-K. If we were to include the cost of stock-based employee compensation in the financial statements, our operating results would decline based on the fair value of the stock-based employee compensation.

Recent Accounting Pronouncements

In October 2001, the Financial Accounting Standards Board issued SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* (SFAS No. 144), which is effective for fiscal years beginning after December 15, 2001 and interim periods within those fiscal periods. SFAS No. 144 supersedes FASB Statement No. 121, *Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of* and addresses financial accounting and reporting for the impairment of certain long-lived assets and for the disposal of long-lived. We do not expect the adoption of SFAS No. 144 to have a material impact on our financial position and results of operations.

In November 2001, the Emerging Issues Task Force (EITF) issued EITF Issue No. 01-09, *Accounting for Consideration Given by a Vendor to a Customer/ Reseller* (EITF 01-09), which addresses the accounting for consideration given by a vendor to a customer, including both a reseller of the vendor s products and an entity that purchases the vendor s products from a reseller. EITF 01-09 also codifies and reconciles related guidance issued by the EITF, including EITF No. 00-25, *Vendor Income Statement Characterization of Consideration Paid to a Reseller of the Vendor s Products* (EITF 00-25). EITF 01-09 outlines the presumption that consideration given by a vendor to a customer, a reseller or a customer of a reseller is to be treated as a deduction from revenue. Treatment of such payments as an expense would only be appropriate if two conditions are met: (i) the vendor receives an identifiable benefit in return for the consideration paid that is sufficiently separable from the sale such that the vendor could have entered into an exchange transaction with a party other than the purchaser or its products in order to receive that benefit; and (ii) the vendor can reasonably estimate the fair value of that benefit. EITF 01-09 is effective for fiscal years beginning after December 15, 2001. We will adopt EITF No. 01-09 beginning with the first quarter of fiscal 2003. We do not expect the adoption of EITF No. 01-09 to have a material impact on our financial position and results of operations.

Factors Affecting Future Operating Results

We have limited experience in the testing services business, and if this business is not successful, we may be harmed

Our WellCheck testing services business, which we acquired in January 2000, is still relatively new to us and to our management team. This will make it more difficult for us to successfully develop this

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business. Also, we will be devoting significant resources to developing this business. If we are not successful in developing this business, our Diagnostic Products business may be harmed. Even if we are successful at developing this business, the demands of attempting to grow this business may prevent us from devoting significant time and attention to our traditional Diagnostic Products business, and that business may decline.

Our operating results may suffer if we are unable to manage geographically diverse operations

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

Our testing services business requires significant management attention and financial resources to develop and if this business is not successful, our business may be harmed

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

If we are unable to expand third party sponsorship of our testing services business, or our existing sponsorship is eliminated or reduced, our revenue will be greatly reduced and our testing services business will fail

WellCheck derives the majority of its revenue from third parties using our testing services to promote their products. For our testing services business to succeed, we must increase and diversify the current number of third-party relationships to grow our business. We are currently in discussions with potential third-party sponsors to establish relationships with WellCheck and have signed contracts with several new third-party sponsors in our continuing efforts to diversify our revenue base. If existing sponsors decline to participate in the future or reduce the amount of their sponsorship, our revenue will be greatly reduced and our testing services business will fail.

If we fail to integrate any future acquisitions, our business will be harmed

We continue to evaluate strategic opportunities available to us and we may pursue product, technology or business acquisitions. These acquisitions could be very costly, could result in dilution to existing investors and could result in integration problems that harm our business as a whole. Any acquisition could result in expending significant amounts of cash, issuing potentially dilutive equity securities or incurring debt or unknown liabilities associated with the acquired business. Any of these acquisition financing approaches could materially harm our operating results and business. Acquisitions may also result

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

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

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

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

the LDX System s accuracy, ease of use, rapid test time, reliability and cost effectiveness compared to other testing alternatives;

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

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

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

If we do not achieve broader market acceptance, our Diagnostic Products business will not grow. Even if we are successful in continuing to place LDX Analyzers at physician office laboratories and other near-patient testing sites, there can be no assurance that placement of LDX Analyzers will result in sustained demand for our single-use test cassettes. We are relying in significant part on income from the core Diagnostic Product business to finance our strategic expansion. If the Diagnostic Products business does not grow, the testing services business will not succeed. These results would cause severe financial harm to us.

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

Our business has experienced a history of operating losses and fluctuating operating results, which may cause our stock price to fall

Historically, we have experienced significant operating losses and negative cash flows from operations. As of March 29, 2002, we had an accumulated deficit of $42.5 million. Our first profitable quarter was the third quarter of fiscal 1998, and our first profitable year was fiscal 1998. We recorded a net

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loss of $2.6 million for fiscal 2001 and a net profit of $5.6 million for fiscal 2002. Our profitability and positive cash flows from operations in the future will require:

broadening market acceptance of our existing product offerings;

successfully developing, introducing and marketing additional test cassettes or other products for our Diagnostic Products business; and

successfully developing our testing services business.

Our quarterly operating results may fluctuate on a quarter to quarter basis, which could cause our stock price to decline

Our revenues and operating results have varied significantly from quarter to quarter in the past and may continue to fluctuate in the future. The following are among the factors that could cause our revenues, operating results and margins to fluctuate significantly from quarter to quarter:

the timing and amount of expenditures required for the continued development of our testing services business;

the timing and level of market acceptance of the LDX System;

the timing of the introduction and availability of new tests;

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

the timing and level of expenditures associated with expansion of sales and marketing activities and overall operations;

variations in manufacturing efficiencies;

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

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

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

product pricing and discounts;

the timing and level of third-party sponsorship of our testing services business;

seasonality of our testing business;

variations in the mix of products sold; and

general economic conditions.

These and other factors are difficult to predict and could have a material adverse effect on our business, financial condition and operating results. Fluctuations in quarterly demand for our products may cause our manufacturing operations to fluctuate in volume, increase uncertainty in operational planning and/or affect cash flows from operations. Many of our expenses are committed to in advance, based on our expectations of future business needs. These costs are largely fixed in the short term. As a result, when business levels do not meet expectations, our fixed costs will not be recovered and we will experience losses. This situation is likely to result in the future because of the variability and unpredictability of our

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revenue. This also means that our results will likely not meet the expectations of public market security analysts or investors at one time or another, which could cause the trading price of our common stock to decline significantly.

If we do not successfully develop, introduce and market new tests, our business will be harmed

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

research and development is a very expensive process;

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

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

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

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

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

new tests must obtain proper regulatory approvals to be marketed.

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

We face risks from failures in our manufacturing processes

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

raw materials variations or impurities;

manufacturing process variances and impurities; and

decreased manufacturing equipment performance.

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

- as our production levels have increased, we have been required to use our machinery more hours per day and the down time resulting from equipment failure has increased;
- the custom nature of much of our manufacturing equipment increases the time required to remedy equipment failures and replace equipment;
- we have a limited number of associates dedicated to the operation and maintenance of our manufacturing equipment, the loss of whom could impact our ability to effectively operate and service such equipment; and
- we manufacture all cassettes at our Hayward, California manufacturing facility, so manufacturing operations are at risk to interruption from earthquake, fire, power outages or other events affecting this one location.
- we are currently in the process of scaling up our recently installed third manufacturing line to full production capability. Our failure to increase production levels and operate this line at full production capability for an extended period would impact our ability to increase our manufacturing capacity.

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

We believe we will be required to reduce manufacturing costs for new and existing test cassettes to achieve sustained profitability. We currently operate three manufacturing lines for dry chemistry cassettes. We have recently installed our third manufacturing line, and we are currently in the process of scaling it up to full production capability. The complexity and custom nature of our manufacturing process increases the amount of time and money required to add an additional manufacturing line. Despite our efforts, the new manufacturing line may not operate at full production volume for a substantial period of time. Also, we may need to implement additional cassette manufacturing cost reduction programs. Failure to fully integrate the new dry chemistry manufacturing line could prevent us from satisfying customer orders in a timely manner, which could lead to customer dissatisfaction and loss of business. Failure to fully integrate the new line could also prevent us from reducing manufacturing costs for dry chemistry tests, and prevent us from achieving sustained profitability.

We depend on single source suppliers for inputs to our manufacturing process and failure of our suppliers to provide supplies to us could harm our business

We currently depend on single source vendors to provide certain subassemblies, components and raw materials used in the manufacture of our products. Any supply interruption in a single source subassembly, component or raw material could restrict our ability to manufacture products until a new source of supply is identified and qualified. We may not be successful in qualifying additional sources of supply on a timely basis, or at all. Failure to obtain a usable alternative source could prevent us from manufacturing our products, resulting in inability to fill orders, customer dissatisfaction and loss of business. This would likely severely harm our business. In addition, an uncorrected impurity or supplier s variation in a raw material, either unknown to us or incompatible with our manufacturing process, could interfere with our

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ability to manufacture products. Because we are a small customer of many of our suppliers and we purchase their subassemblies, components and materials with purchase orders instead of long-term commitments, our suppliers may not devote adequate resources to supplying our needs. Any interruption or reduction in the future supply of any subassemblies, components or raw materials currently obtained from single or limited sources could severely harm our business.

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

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

We depend on distributors to sell our products and will need to maintain and expand these existing relationships

To increase revenue and achieve sustained profitability, we will have to maintain and expand our existing distribution relationships and develop new distribution relationships. We are dependent on such distributors to assist us in promoting market acceptance of the LDX System. If we do not maintain and expand these relationships, our sales will not grow and our business will be greatly harmed. Also, we may be unable to enter into and maintain new arrangements on a timely basis, or at all. Even if we do enter into additional distributor relationships, those distributors may not devote the resources necessary to provide effective sales and marketing support to our products. We do not have the ability to prevent distributors from distributing products that compete with our products. The distributors may also give higher priority to the products of our competitors.

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

Sales to a limited number of customers have accounted for a significant portion of our revenue in each fiscal period. We have experienced periods in which sales to some of our major customers, as a percentage of total revenue, have fluctuated due to delays or failures to place expected orders. We expect that sales to a limited number of customers will continue to account for a substantial portion of our total revenue in future periods. Our top ten customers comprised 67% of our revenue in fiscal 2002. In fiscal 2002, Physician Sales and Service, Inc. (PSSI) accounted for approximately 18% of our total revenue and GMR Marketing (GMR) accounted for 14% of our total revenue. In fiscal 2001, PSSI accounted for approximately 16% of our total revenue and GMR accounted for approximately 7% of our total revenue. We do not have long-term agreements with any of our customers. Customers generally purchase our products pursuant to cancelable short-term purchase orders. If we were to lose a major customer or if orders by or shipments to a major customer were to otherwise decrease or be delayed, our results of operations would be harmed.

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

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

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

- third party payors increasingly scrutinize and challenge the prices charged for medical products and services;
- healthcare providers are moving toward a managed care system in which they provide comprehensive healthcare for a fixed cost per patient and authorize fewer elective procedures, such as uses of our products for diagnostic screening;
- general uncertainty regarding what changes will be made in the reimbursement methods used by third party payors and how that will affect use of products such as ours, which may deter healthcare providers from adopting the use of our products; and
- an overall escalating cost of medical products and services has led to and will continue to lead to increased pressures on the healthcare industry, both domestic and international, to reduce the cost of products and services, including products offered by us.

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

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

We believe that the healthcare industry in the United States of America is likely to undergo fundamental changes due to current political, economic and regulatory influences. We anticipate that Congress, state legislatures and the private sector will continue to review and assess alternative healthcare delivery and payment systems. Potential alternatives include mandated basic healthcare benefits, controls on healthcare spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, the creation of large insurance purchasing groups, price controls and other fundamental changes to the healthcare delivery system. We expect legislative debate to continue in the

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future and for market forces to demand reduced costs. We cannot predict what impact the adoption of any federal or state healthcare reform measures, future private sector reform or market forces may have on our business. Any changes in the healthcare system could potentially have extremely negative effects on our business.

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

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

In addition, any future amendment of or addition to regulations impacting our products could prevent us from marketing the LDX System. Regulatory changes could hurt our business by increasing burdens on our products or by reducing or eliminating certain competitive advantages of the LDX System s waived status. Food and Drug Administration clearance or approval of products such as ours can be obtained by either of two processes:

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

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

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

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

The LDX Analyzer, our total cholesterol, high density lipoproteins, triglycerides and glucose tests in any combination and our ALT test cassette have been classified as waived from the application of many of the requirements under the Clinical Laboratory Improvement Amendments. We believe this waived classification is critical for our products to be successful in their markets. Any failure of our new tests to obtain waived status under the Clinical Laboratory Improvement Amendments will severely limit our ability to

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commercialize such tests. Loss of waived status for existing diagnostic products or failure to obtain waived status for new products could limit our revenue, which would severely harm our business.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In the past, patent infringement claims have been asserted against us. On December 23, 1999, a complaint entitled Roche Diagnostics GmbH v. Health Care Solutions AG, Euredix N.V./SA and Cholestech Corporation was filed with the Canton Court of the Canton Zug in Zug, Switzerland by Roche Diagnostics seeking a cease and desist order barring us and two of our distributors from distributing HDL assay single-use test cassettes in Switzerland. The complaint alleges that we violated a Roche European patent for HDL. On July 11, 2000, the court denied the plaintiff 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 us and ordered the plaintiff to pay our legal fees. There can be no assurance as to whether the plaintiff will appeal this ruling or whether any additional action will be resolved in our favor.

Additionally, in January 2000, a complaint was filed in the District Court, Dusseldorf, Germany against us and two of our distributors seeking a cease and desist order barring the distributors from shipping HDL single-use test cassettes into Germany. The complaint alleges we and our distributors violated a Roche German priority patent for HDL by selling our single-use test cassette containing a HDL assay. On December 4, 2001, a hearing was held in Dusseldorf, Germany at which Cholestech and Roche witnesses testified. A hearing has been set for September 3, 2002. In September 2000, we were served a complaint, No. Ei/Ti ROCH 04002, filed in Vienna, Austria by Roche Diagnostics, seeking a cease and desist order barring us and one of our distributors from distributing HDL assay single-use test cassettes in Austria. The complaint alleges that we violated a Roche European patent for HDL. At this point, no schedule has been set regarding court activity. We believe all suits are without merit and intend to defend the cases vigorously. We do not believe that we engaged in any wrongdoing and that the outcome of this matter will not result in a material adverse effect; however, there can be no assurance that the lawsuits will be resolved in our favor.

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

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

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

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the operation of our business. Failure to obtain adequate licenses on commercially reasonable terms could prevent us from producing our products and severely harm our business.

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

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

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

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

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

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

We currently maintain product liability and professional liability insurance, but there can be no assurance that the coverage limits of our insurance policies will be adequate. Insurance is expensive and

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difficult to obtain, and we may be unable to maintain product liability insurance in the future on acceptable terms or in sufficient amounts to protect us against losses due to product liability. Inability to maintain insurance at an acceptable cost or to otherwise protect against potential product liability could prevent or inhibit the continued commercialization of our products. In addition, a product liability or professional liability claim in excess of relevant insurance coverage or a product recall could severely hurt our financial condition.

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

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

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

We have made use of devices to limit the possibility that we are acquired, which may mean that a transaction that shareholders are in favor of or are benefited by may be prevented

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

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

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

- quarterly variations in our results of operations;
- announcements of technological or competitive developments by us and our competitors;
- regulatory developments regarding us or our competitors;
- changes in the current structure of the healthcare financing and payment systems;
- developments in or disputes regarding patent or other proprietary rights;
- stock market price and volume fluctuations, which have particularly affected the market prices for medical products and high technology companies and which are often been unrelated to the operating performance of such companies; and
- general economic, political and market conditions.

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Quantitative Disclosures

Our exposure to market risks is inherent in our operations, primarily to interest rates relating to our investment portfolio. We do not use derivative financial instruments in our investment portfolio and had no holdings of derivative financial or commodity instruments as of March 29, 2002.

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

We have concluded that the fair market value of our investment portfolio or related income would not be significantly impacted by changes in interest rates due to the nature of our marketable securities, which do not mature beyond fiscal 2004 and have primarily fixed interest rates.

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

	2003	2004	Total	Fair Value
			(In thousands)	
Cash, cash equivalents	$8,800	$	$8,800	$8,800
Short-term marketable securities	$8,227		$8,227	$8,227
Weighted average interest rate	2.78%			