CHOLESTECH CORPORATION
Form 10-K
June 08, 2005

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

(Mark One)

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

or

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

Commission File Number: 000-20198

CHOLESTECH CORPORATION

(Exact name of registrant as specified in its charter)

CALIFORNIA	**94-3065493**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
3347 INVESTMENT BOULEVARD HAYWARD, CALIFORNIA	**94545**
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code: **(510) 732-7200**
Securities registered pursuant to Section 12(b) of the Act: **None**
Securities registered pursuant to Section 12(g) of the Act:
COMMON STOCK, NO PAR VALUE
SERIES A PARTICIPATING PREFERRED STOCK, NO PAR VALUE
(Title of Class)

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

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

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

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

As of May 31, 2005, the registrant had outstanding 14,648,713 shares of common stock.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant has incorporated by reference into Part III of this Annual Report on Form 10-K portions of its Proxy Statement for the 2005 Annual Meeting of Shareholders to be held August 17, 2005.

Cholestech Corporation
Annual Report on Form 10-K
For The Fiscal Year Ended March 25, 2005
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Part I

Some of the statements contained in this Annual Report on Form 10-K are forward-looking statements about Cholestech Corporation (we, us or Cholestech), including but not limited to those specifically identified as such, that involve risks and uncertainties. The statements contained in the Report on Form 10-K that are not purely historical are forward looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, including, without limitation, statements regarding our expectations, beliefs, intentions or strategies regarding the future. All forward-looking statements included in this Report on Form 10-K are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors, which may cause our actual results to differ materially from those implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as may, will, should, expects, plans, anticipates, estimates, predicts, potential or continue or the negative of these terms or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Moreover, neither any other person nor we assume responsibility for the accuracy and completeness of such statements. Important factors that may cause actual results to differ from expectations include those discussed in Factors Affecting Future Operating Results beginning on page 38 in this document.

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

Item 1. Business

OVERVIEW

We are a leading provider of diagnostic tools and information for immediate risk assessment and therapeutic monitoring of heart disease and diabetes. We currently manufacture the LDX® System (the LDX System), which includes the LDX Analyzer and a variety of single-use test cassettes and market the LDX System in the United States, Europe, Asia, Australia and South America. The LDX System, which is waived under the Clinical Laboratory Improvement Amendments (CLIA), allows healthcare providers to perform individual tests or combinations of tests with a single drop of blood from a fingerstick within five minutes. Our current products measure and monitor blood cholesterol, related lipids, glucose and liver function, and are used to test patients at risk of or suffering from heart disease, diabetes and liver disease. The LDX System can also provide the Framingham Risk Assessment from the patient s results as measured on the lipid profile cassette. In fiscal year 2005, revenue from sales of the LDX Analyzer and single use test cassettes represented over 90% of our revenue.

We also market and distribute the GDX™ System (the GDX System) under a multi-year global distribution agreement with Provalis Diagnostics Ltd. We began distributing the GDX System under this agreement in July 2002. The Cholestech GDX is a hemoglobin A1c (A1C) testing system that is also waived under CLIA and is used to measure A1C in less than five minutes using a single drop of blood from a fingerstick. The quantitative measure of A1C is well-established as an indicator of a patient s long-term glycemic control. Unlike daily glucose monitoring, which provides a snapshot of a patient s glucose level at the time of testing, A1C provides an average glucose level over the previous 90 days. A1C levels indicate the long-term progress of a patient s diabetes and therapy management.

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

We specifically target our products for markets outside of traditional hospital or clinical laboratories through our worldwide network of over 85 distributors. Our primary market is the physician office laboratory market, which consists of approximately 104,000 sites operated by physicians or groups of physicians that are registered with the Centers for Medicare & Medicaid Services (CMS), approximately 51,000 of which are registered to perform only tests that have been waived under CLIA. According to CMS, the number of CLIA waived physician office laboratories has increased 27% since 2000.

Sales of our products to international markets represented 14% of our revenue in fiscal year 2005. While a majority of such sales are in Europe, we are expanding into Asia, and South America. See Note 10 of the consolidated Financial Statements for details on our international revenue.

Providing rapid service to our customers is one of the fundamentals of our business. Generally we fulfill our customers orders within two business days of the placement of an order, resulting in no material backlog as of March 25, 2005. Although there are certain months of the year in which testing for cholesterol typically increases, such as September which is National Cholesterol Month and February which is National Heart Month, historically we have not experienced fluctuations in sales of our products due to seasonality.

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

MARKET OVERVIEW

We believe the market for our products exists where healthcare providers, as well as healthcare product and service organizations, seek to identify, treat and monitor individuals with chronic conditions such as heart disease and diabetes. High cholesterol is a significant contributing factor to cardiovascular disease, which remains the leading cause of death in the United States and kills more people than the next five diseases combined. Heart disease is also the leading cause of death among diabetics.

In 2002, the estimated cost in the United States of coronary heart disease and diabetes was $244 billion.

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The American Heart Association estimates that more than 70 million people suffer from some form of cardiovascular disease, which is the leading cause of death of adults in the United States.

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

Based on evidence from scientific studies, the National Cholesterol Education Program (NCEP) expert panel and the National Institutes of Health (NIH) issued guidelines in May 2001 which are expected to substantially increase the number of Americans being treated for high cholesterol. Numerous research studies substantiate that reducing high cholesterol levels reduces the risk of a coronary event by 31%. NIH guidelines continue to encourage the increase of cholesterol testing as the recommended LDL levels decreased from 100 to 80 in 2004.

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

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

OUR STRATEGY

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

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

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

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

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

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PRODUCTS AND PRODUCTS UNDER DEVELOPMENT

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

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

Our research and development expenses were $4.3 million, $3.2 million and $2.7 million for fiscal years 2005, 2004 and 2003, respectively.

Overview of the Cholestech LDX System

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

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

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

The LDX Analyzer

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

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the amount of light reflected from the reaction surfaces of a test cassette and incorporates a microprocessor with built-in software. The LDX Analyzer contains a drawer for insertion of the cassette, three buttons for user activation and a liquid crystal display to present the test results. Using the information and instructions encoded on the cassette s magnetic strip, the LDX Analyzer s built-in microprocessor regulates the reaction conditions, controls the optical measurements of analyte concentrations on the cassette s reaction pads, executes the required calculations and, within five minutes, displays the results on the liquid crystal display. The results are displayed as a numerical value of the level of the analyte tested and can be transferred to a printer, computer or computer network.

The built-in software calculates the numeric values of the test results and is contained in a removable read only memory software pack mounted in an access well on the bottom of the LDX Analyzer. We upgrade the software as new products are developed, allowing healthcare providers to easily replace the existing read only memory pack with a new pack containing upgraded software. The LDX Analyzer, along with a printer, accessories and starter pack, comprises a LDX System and currently has a domestic list price of $2,055.

Cassette Products

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

Overview of the Cholestech GDX System

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

The GDX Analyzer

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

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

Cartridge Product

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

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

Product	Regulatory Status (1)
Instrument	
LDX Analyzer	FDA cleared; CLIA waived
GDX Analyzer	FDA cleared, CLIA waived
Endo-PAT	510(k) cleared
Cassette Products	
Current	
Lipid Profile (Lipid)	FDA cleared; CLIA waived
(Total cholesterol/ High density lipoproteins/ Calculated low density lipoproteins/ Triglycerides)	
Lipid Profile plus Glucose (Lipid/ GLU)	FDA cleared; CLIA waived
Total Cholesterol and Glucose (TC, GLU)	FDA cleared; CLIA waived
Total Cholesterol/ High Density Lipoproteins/ Glucose (TC, HDL, GLU)	FDA cleared; CLIA waived
Total Cholesterol and High Density Lipoproteins (TC, HDL)	FDA cleared; CLIA waived
Total Cholesterol (TC)	FDA cleared; CLIA waived
Alanine Aminotransferase (ALT)/ Aspartate Aminotransferase (AST)	FDA cleared, CLIA waived
Under Development (2)	
High Sensitivity C-Reactive Protein (HS-CRP)	510(k) cleared
Lipid Profile Alanine Aminotransferase (Lipid/ ALT)	No regulatory filing required
In Feasibility Studies (3)	
Total Bilirubin (Tbil)	Not filed or applied
Alkaline Phosphate (ALP)	Not filed or applied
Creatine Kinase (CK)	Not filed or applied
Direct Low Density Lipoproteins (LDL)	Not filed or applied
Hemoglobin A1c (A1C)	Not filed or applied
Cartridge Product	
Hemoglobin A1c (A1C)	FDA cleared; CLIA waived

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

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

launch.

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

Current Cassette and Cartridge Products

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

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

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

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

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

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

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

Cassette Products Under Development

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

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

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

Lipid Profile/Alanine Aminotransferase. We plan to offer a single cassette containing both our CLIA waived lipid profile and ALT tests (Lipid/ALT). The integration of the lipid parameters (total cholesterol, HDL cholesterol and triglycerides) and liver function parameter (ALT) will provide convenience and ease of use for our customers. We expect this product to be available in late calendar year 2005.

Cassette Products in Feasibility Studies

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

Liver Panel

ALT/ AST.

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

Alkaline Phosphatase. Alkaline phosphatase is a group of enzymes that are active at an alkaline pH. Alkaline phosphatase activity is highest in the liver, bone, intestine and kidney and is a useful test of liver function. Measurement of alkaline phosphatase in the blood in differentiating hepatobiliary disease from osteogenic bone disease.

Statin Safety Panel

ALT/ AST.

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

Individual Test Cassettes

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

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

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Other Platforms

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

STRATEGIC RELATIONSHIPS

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

Distribution

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

ImpactHealth.com, Inc.

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

Itamar Medical

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

Marketing Programs

Our LDX System continues to be utilized in a number of regionally based marketing programs in the United States, including healthcare industry conventions. Our international sales and marketing team continues to work with selected global pharmaceutical companies in connection with country specific marketing programs. Pharmaceutical companies utilizing our LDX System in connection with such programs include AstraZeneca PLC and Pfizer Inc.

SALES AND MARKETING

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

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Our sales and marketing strategy includes increasing penetration into the physician office laboratory and health promotion markets and leveraging our installed base of LDX and GDX Analyzers. We plan to dedicate a significant portion of our sales and marketing efforts to educate current and potential customers about the clinical and economic benefits of diagnostic screening and therapeutic monitoring and about new test cassettes as they become available for distribution. In order to support this effort, over the last year we hired representatives who focus on calling our key accounts by phone. We also plan to continue to cultivate strategic relationships with development partners, pharmaceutical companies and distributors. We intend to leverage the technology, customer base, marketing power and distribution networks of these partners to accelerate market penetration and increase cassette usage. Our current marketing activities are primarily focused on:

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

Health Promotion. We have ongoing relationships with approximately 15 regional distributors whose primary focus are to provide equipment and supplies to customers that conduct diagnostic screening for cholesterol and related lipid levels and diabetes. Some of these distributors also sell to the POL market segment.

International. Our international distribution strategy is to penetrate targeted geographical markets by selling directly to distributors in those markets. We have entered into non-exclusive agreements with approximately 35 foreign distributors to distribute the LDX System and cassettes primarily in Europe, Asia and South America.

COMPETITION

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

Companies with a significant presence in the diagnostic products market, such as Abbott Laboratories, Bayer Diagnostics, Beckman Coulter, Inc. and Roche Diagnostics (a subsidiary of Roche Holdings Ltd.), have developed or are developing analyzers designed for point of care testing. Such competitors also offer broader product lines than us, have greater name recognition than us and offer discounts as a competitive tactic. In addition, several smaller companies are currently making or developing products that compete or will compete with ours. We believe we currently have a competitive advantage due to (i) the status of the

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LDX System which is waived under CLIA and can provide a complete lipid profile in accordance with the NIH guidelines in less than five minutes using a single drop of blood; (ii) our ALT test, which is the only ALT test waived under CLIA by the FDA and enables physicians to monitor the potential side effects on the liver from cholesterol lowering drugs and other medications; (iii) the improving breadth of the CLIA waived tests that we offer our installed base; and (iv) our network of over 85 distributors. We expect that our competitors will compete actively to maintain and increase market share and will seek to develop multi-analyte tests that qualify for CLIA waiver.

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

MANUFACTURING

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

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

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

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

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source vendors and on a purchase order basis. Our quality assurance personnel also perform finished goods quality control and inspection and maintain documentation for compliance with quality systems regulations and other government manufacturing regulations.

PATENTS AND PROPRIETARY TECHNOLOGY

We have 10 patents in the United States covering various technologies, including the method for separating HDL from other lipoproteins in a dry chemistry format, the basic design of the testing cassette and the LDX Analyzer and the method of correcting for the effects of substances that can interfere with testing of a blood sample. We have filed four additional patent applications in the United States and internationally under the Patent Cooperation Treaty and individual foreign applications. We are also the licensee of United States patents relating to the measurement of Lp(a) and a portion of our cassette technology.

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

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

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

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

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GOVERNMENT REGULATION

Food and Drug Administration and Other Regulations

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

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

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

In general, we intend to develop and market tests that will receive 510(k) clearance. However, if we cannot establish that a proposed test cassette is substantially equivalent to a legally marketed device, we will be required to seek pre-market approval of the proposed test cassette from the FDA through the submission of a pre-market approval application. If a future product were to require submission of this type of application, regulatory approval of such product would involve a much longer and more costly process than a 510(k) clearance. We do not believe that our products under development will require the submission of a pre-market approval application, which can be lengthy, expensive and uncertain. A FDA review of a pre-market approval application generally takes one to three years from the date it is accepted for filing, but may take significantly longer.

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

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

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

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

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

Clinical Laboratory Improvement Amendments, 1988

The use of our products in the United States is subject to CLIA, which provides for federal regulation of laboratory testing, an activity also regulated by most states. Laboratories must obtain either a Certificate of Waiver or a registration certificate (for moderately complex testing) from CMS. Some states may require a state license also. The CLIA regulations seek to ensure the quality of medical testing. The three primary mechanisms to accomplish this goal are daily quality control requirements to ensure the accuracy of

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laboratory devices and procedures, proficiency testing to measure testing accuracy and personnel standards to assure appropriate training and experience for laboratory workers. CLIA categorizes tests as waived, or as being moderately complex or highly complex on the basis of specific criteria. To successfully commercialize tests that are currently under development, we believe it will be critical to obtain waived classification for such tests under CLIA, because CLIA waiver allows healthcare providers to use the LDX System with fewer requirements and at a lower cost.

THIRD PARTY REIMBURSEMENT

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

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

In 1991, the Health Care Finance Administration adopted regulations providing for the inclusion of capital related costs in the prospective payment system for hospital inpatient services under which most hospitals are reimbursed by Medicare on a per diagnosis basis at fixed rates unrelated to actual costs, based on diagnostic related groups. Under this system of reimbursement, equipment costs generally are not reimbursed separately, but rather are included in a single, fixed rate, per patient reimbursement. Medicare reform legislation requires CMS to implement a prospective payment system for outpatient hospital services as well. This system may also provide for a per-patient fixed rate reimbursement for outpatient department capital costs. We believe these regulations place more pressure on hospitals operating margins, causing them to limit capital expenditures. These regulations could have an adverse effect on us if hospitals decide

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

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

PRODUCT LIABILITY AND INSURANCE

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

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

EMPLOYEES

As of March 25, 2005, we employed 204 full-time associates. There were 93 employees in manufacturing, 48 employees in sales and marketing, 31 employees in administration and 32 employees in research and development. None of our associates are covered by a collective bargaining agreement, and management considers relations with employees to be excellent.

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EXECUTIVE OFFICERS

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

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