

CHOLESTECH CORPORATION
Form 10-K
June 13, 2007

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE FISCAL YEAR ENDED MARCH 30, 2007

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM _____ TO _____

Commission file number: 000-20198

CHOLESTECH CORPORATION

(Exact name of registrant as specified in its charter)

California
(State or other jurisdiction of incorporation or organization)
3347 Investment Boulevard
Hayward, California
(Address of principal executive offices)

94-3065493
(I.R.S. Employer Identification No.)

94545
(Zip Code)

Registrant's telephone number, including area code:

(510) 732-7200

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

Title of each class
Common Stock, no par value
Series A Participating Preferred Stock, no par value

Name of each exchange on which registered:
The NASDAQ Stock Market LLC
(The NASDAQ-GM)

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes No

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

The aggregate market value of the voting stock held by non-affiliates of the registrant, based on the closing sale price of the common stock on September 29, 2006 as reported on the NASDAQ Stock Market LLC, was approximately \$159,656,000. 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, 2007, the registrant had outstanding 15,585,369 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 or Information Statement to be filed pursuant to Regulations 14A or 14C, no later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

CHOLESTECH CORPORATION
ANNUAL REPORT ON FORM 10-K
For The Fiscal Year Ended March 30, 2007
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Cholestech LDX and Cholestech GDX, are trademarks belonging to Cholestech Corporation and are pending or registered in the United States and other countries.

PART I

Some of the statements contained in this Annual Report on Form 10-K are forward-looking statements about Cholestech Corporation (we, us, Cholestech, or the Company), including but not limited to those specifically identified as such, that involve risks and uncertainties. The statements contained in this Annual Report on Form 10-K that are not purely historical are forward looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Exchange Act of 1934, as amended, including, without limitation, statements regarding our expectations, beliefs, intentions or strategies regarding the future. All forward-looking statements included in this Annual Report on Form 10-K are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors, which may cause our actual results to differ materially from those implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as may, will, should, expects, plans, anticipates, believes, estimates, predicts, potential or continue or the negative of these terms or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Moreover, neither any other person nor we assume responsibility for the accuracy and completeness of such statements. Important factors that may cause actual results to differ from expectations include those discussed in Item 1A: Risk Factors beginning on page 20 in this document, as well as those factors identified from time to time in our periodic filings with the Securities and Exchange Commission (SEC).

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, inflammatory disorders and diabetes. We currently manufacture the Cholestech 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 Coronary Heart Disease Risk Assessment from the patient s results as measured on the lipid profile cassette. In fiscal year 2007, revenue from sales of the LDX Analyzer and single use test cassettes represented over 90% of our revenue.

We also market and distribute the Cholestech GDX System (the GDX System) under a multi-year global distribution agreement with with Provalis Diagnostics Ltd, who was acquired by Bio-Rad Laboratories, Inc. on September 7, 2006. We began distributing the GDX System under this agreement in July 2002. The Cholestech GDX, a hemoglobin A1c (A1C) testing system, is FDA 510(k) cleared for prescription home use and, accordingly, is CLIA waived . It 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.

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 117,000 sites operated by physicians or groups of physicians that are registered with the Centers for Medicare & Medicaid Services (CMS). Approximately 54,000 of these 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 31% since 2000.

Sales of our products to international markets represented 13% of our revenue in fiscal year 2007. While a majority of such sales are in Europe, we are expanding into Asia, and South America. See Note 10 of the 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 30, 2007. 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 effort by major pharmaceutical companies to obtain 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.

Recent Developments

On June 4, 2007, Cholestech, Inverness Medical Innovations, Inc., a Delaware corporation (Inverness), and Iris Merger Sub, Inc., a California corporation and wholly owned subsidiary of Inverness (Merger Sub), entered into an Agreement and Plan of Reorganization (the Merger Agreement), pursuant to which Cholestech and Inverness will combine their businesses through a merger of Cholestech and Merger Sub (the Merger).

The completion of the Merger is subject to various closing conditions, including obtaining the approval of Cholestech shareholders and receiving antitrust approvals (including under the Hart-Scott-Rodino Antitrust Improvements Act). The Merger is intended to qualify as a reorganization for federal income tax purposes.

At the effective time of the Merger (the **Effective Time**), by virtue of the Merger and without any action on the part of the holder of any capital stock of Cholestech, each share of common stock of Cholestech issued and outstanding immediately prior to the Effective Time will be converted into the right to receive 0.43642 (the **Exchange Ratio**) of a share of common stock of Inverness (each full share, an **Inverness Share**).

In the Merger, each option to purchase shares of Cholestech common stock granted under employee and director stock plans of Cholestech that is outstanding as of immediately prior to the Effective Time, whether vested or unvested, shall be converted into a right to acquire Inverness Shares on the same terms and conditions as were applicable to such option prior to the Effective Time, provided that the number of Inverness Shares receivable and the exercise price of the option shall be adjusted to reflect the Exchange Ratio. All other Cholestech equity-based awards outstanding as of the Effective Time will remain in effect but will be denominated in Inverness Shares, with applicable adjustments to reflect the Exchange Ratio.

If the Merger Agreement is terminated under certain circumstances specified in the Merger Agreement, Cholestech will be required to pay Inverness a termination fee of \$9 million.

The Boards of Directors of Cholestech and Inverness have approved the Merger and the Merger Agreement.

The foregoing description of the Merger Agreement is qualified in its entirety by reference to the full text of the Merger Agreement, which is attached to this Annual Report on Form 10-K as Exhibit 2.1 and incorporated herein by reference. The Merger Agreement has been attached to provide investors with information regarding its terms. It is not intended to provide any other factual information about Cholestech or Inverness. In particular, the assertions embodied in the representations and warranties contained in the Merger Agreement are qualified by information in confidential disclosure schedules provided by Cholestech and Inverness to each other in connection with the signing of the Merger Agreement. These disclosure schedules contain information that modifies, qualifies and creates exceptions to the representations and warranties set forth in the Merger Agreement. Moreover, certain representations and warranties in the Merger Agreement were used for the purpose of allocating risk between Cholestech and Inverness rather than establishing matters as facts. Accordingly, you should not rely on the representations and warranties in the Merger Agreement as characterizations of the actual state of facts about Cholestech or Inverness.

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.
- The American Heart Association estimates that more than 79 million people suffer from some form of cardiovascular disease, which is the leading cause of death of adults in the United States.
- 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 substantially increasing 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 cholesterol levels decreased from 100 to 70 mg/dL for certain high risk patients in 2004.

- Based on the NIH guidelines, approximately 220 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 grow to over 65 million. The number of Americans prescribed a cholesterol-lowering drug is expected to grow to over 36 million.
- Diabetes is estimated to afflict approximately 21 million people in the United States, over a third of whom have not yet been identified as being diabetic. Additionally, 54 million Americans require treatment for prevention of diabetes and 97 million should be screened or monitored for diabetes risk based on data and recommendations from the American Diabetes Association and the U.S. Department of Health and Human Services.
- 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.

Our Strategy

Our objective 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 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 a new test cassette for 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.

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 Bio-Rad Laboratories, Inc. 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 \$6.3 million, \$7.6 million, and \$4.3 million for fiscal year 2007, fiscal year 2006, and fiscal year 2005, 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 5%, 5%, and 6% of total revenue in fiscal year 2007, fiscal year 2006, and fiscal year 2005, respectively. The LDX Analyzer is a proprietary, 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 \$2,115.

Cassette Products

Revenue from cassette products represented 85%, 84%, and 83% of total revenue in fiscal year 2007, fiscal year 2006, and fiscal year 2005, 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 \$4.19 to \$13.00 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-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

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

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
VasoSense	FDA cleared
Cassette Products	
<i>Current</i>	
Lipid Profile (Lipid) (Total cholesterol/High density lipoproteins/Glucose/Triglyceride/Estimated LDL cholesterol/and TC/HDL ratio)	FDA cleared; CLIA waived
Lipid Profile plus Glucose (Lipid/GLU)	FDA cleared; CLIA waived
Total Cholesterol and Glucose (TC, GLU)	FDA cleared; CLIA waived
Total Cholesterol/High Density Lipoproteins/Glucose (TC, HDL, GLU)	FDA cleared; CLIA waived
Total Cholesterol and High Density Lipoproteins (TC, HDL)	FDA cleared; CLIA waived
Total Cholesterol (TC)	FDA cleared; CLIA waived
Alanine Aminotransferase (ALT)/Aspartate Aminotransferase (AST)	FDA cleared; CLIA waived
High Sensitivity C-Reactive Protein (hs-CRP)	FDA cleared
<i>Under Development(2)</i>	
Lipid Profile/Alanine Aminotransferase (Lipid/ALT)	FDA cleared; CLIA waived
<i>In Feasibility Studies(3)</i>	
Total Bilirubin (Tbil)	Not filed or applied
Alkaline Phosphate (ALP)	Not filed or applied
Creatine Kinase (CK)	Not filed or applied
Direct Low Density Lipoproteins (LDL)	Not filed or applied
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.

(4) The GDx system is FDA 510(k) cleared for prescription home use and, accordingly, is CLIA waived.

Current Cassette and Cartridge Products

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

- ***Lipid Profile.*** We offer a lipid profile cassette, which directly measures TC, HDL and triglycerides. This cassette meets all of the screening and monitoring guidelines recommended by the NIH guidelines. In addition, the lipid profile cassette calculates estimated values for LDL and the ratio of TC to HDL. The development of cardiovascular disease has been associated with three lipoprotein abnormalities: high levels of LDL, high levels of very low density lipoproteins (VLDL) and low levels of HDL. LDL, the major carrier of cholesterol and VLDL, a major carrier of triglycerides in the blood, have been shown to be associated with deposits of plaque on the arterial wall. High levels of triglycerides can also lead to development of such plaque. Accumulation of this plaque leads to a narrowing of the arteries and increases the likelihood of cardiovascular disease. The lipid profile cassette thus performs multiple tests in the diagnostic screening and ongoing therapeutic monitoring of individuals who have high LDL levels or who exhibit two or more other cardiovascular disease risk factors. NCEP guidelines recommend that healthcare providers perform two lipid profiles, one to four weeks apart, before initiating lipid lowering drug therapy.
- ***Lipid Profile plus Glucose Panel, Total Cholesterol and Glucose Panel, and Total Cholesterol/High Density Lipoproteins/Glucose Panel.*** Recognizing the relationship between diabetes and abnormal lipid levels, we developed a blood glucose test for the LDX System and combined it with each of its three lipid related test panels. The resulting panels provide input used in the diagnostic screening and therapeutic monitoring of patients with diabetes, whether or not they are aware they are diabetic, as well as individuals who may be at risk of cardiovascular disease.
- ***Total Cholesterol and High Density Lipoproteins Panel.*** The total cholesterol (TC) and high density lipoproteins (HDL) panel is the recommended test under the current NIH guidelines if the individual being screened has not fasted. HDL particles circulate in the blood and can pick up cholesterol from arteries and carry it to the liver for elimination from the body. HDL is sometimes called "good cholesterol" because of this function. This panel also calculates the ratio of TC to HDL, a recognized measure of cholesterol induced cardiac risk.
- ***Total Cholesterol.*** This stand-alone test for measuring TC was our first test, developed in conjunction with NCEP guidelines issued in 1988.
- ***Alanine 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.

- *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 inflammation and the measurement of CRP is useful in the detection and evaluation of infection, tissue injury, inflammatory disorders, and associated diseases.

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. We expect this product to be available in the first quarter of fiscal year 2008.

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 is for 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 certain limitations including the need for a fasting sample. The direct LDL cholesterol test is reimbursable, whereas the calculated test is not.

Other Platforms

- *Vascular Endothelial Dysfunction.* The VasoSense 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.

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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.

Boule Diagnostics

In November 2005, we signed a definitive agreement with Boule Diagnostic International Boule, an international manufacturer of hematology systems, headquartered in Stockholm, Sweden. Under the terms of the agreement, we will collaborate with Boule on the development and commercialization of a point of care Complete Blood Count (CBC) system, designed for waiver under CLIA. We will receive exclusive distribution rights covering all human applications in the United States and Canada.

Itamar Medical

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

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.

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, we have 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 non-exclusive distribution agreements with five national medical products distributors, Cardinal Health, Inc., Fisher Scientific International, Inc., McKesson Corporation, Physician Sales and Service, Inc., and Henry Schein, Inc., which together have more than 2,500 sales professionals who focus primarily on the United States physician office laboratory (POL) market. We have also retained 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 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 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 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, only two other companies have a CLIA waived ALT test that 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 13485:2003, CMDCAS requirements 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 the European In-Vitro Diagnostic Directive, and Canadian CMDCAS requirements including in process and final quality assurance testing. All of 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 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 13 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 that expire between 2009 and 2024. We have filed six 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, Roche Diagnostics and the Company signed a settlement agreement and a license agreement which settled and dismissed all then 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. Under the Roche license and settlement agreements, the Company is entitled to identify a design-around product that we believe does not require license payments to Roche and the Company has done so. Roche can request arbitration on this issue, and they have taken the first steps to initiate such proceedings. If no agreement is reached, an arbitration will be commenced to determine whether license payments must be made for the design-around. If, 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, as that agreed to under the Roche license and settlement agreements.

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.

Our inability to protect our proprietary information could harm our business. Information regarding risks associated with failure to protect our proprietary technology and our intellectual property rights may be found on pages 17 through 28 of this Annual Report on Form 10-K under the heading Risk Factors.

Finally, we believe that certain trademarks of ours are valuable assets that are important to the marketing of our products. Many of these trademarks have been registered with the United States Patent and Trademark Office or internationally, as appropriate.

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 including removal or correction of products, 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.

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. Depending on the type of 510(k) submission filed, it generally takes from two to three 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 (PMA). 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 six months to one year from the date it is accepted for filing, but may take significantly longer.

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

The FDC Act regulates our quality control and manufacturing procedures by requiring us and our contract manufacturers to demonstrate compliance with quality systems regulations. The FDA monitors compliance with these requirements by requiring manufacturers to register with the FDA, which subjects them to periodic inspections. We were inspected by the FDA in 2003 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. Our products sold in the EU have been CE Marked through Annex III of 98/79/EC of the European Parliament and of the Council on in-vitro diagnostic medical devices. 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 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 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 30, 2007, we employed 216 full-time associates. There were 90 employees in manufacturing, 61 employees in sales and marketing, 39 employees in administration and 26 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. We also occasionally utilize the services of temporary and contract employees.

Executive Officers

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

Name	Age	Position
Warren E. Pinckert II	63	President, Chief Executive Officer and Director
John F. Glenn	45	Vice President of Finance, Chief Financial Officer, Treasurer and Secretary
Gregory L. Bennett	45	Vice President of Development
Barbara T. McAleer	49	Vice President of Quality Assurance and Regulatory Affairs
Kenneth F. Miller	51	Vice President of Sales and Marketing
Terry L. Wassmann	60	Vice President of Human Resources
Donald P. Wood	55	Vice President of Operations

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 Advisors for the San Francisco State University School of Business. Mr. Pinckert holds a Bachelor of Science degree in Accounting and a Masters of Business Administration degree from the University of Southern California.

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

Mr. Gregory L. Bennett has served as our Vice President, Development since December 2005. From November 2003 to December 2005, he served as our Director of Engineering, in charge of Process Engineering, Quality Control, Facilities, Product Transfer and Manufacturing Engineering. Prior to joining Cholestech, Mr. Bennett was Director of Process Development Engineering for LifeScan Inc., a Johnson & Johnson company. Before this position, Mr. Bennett held a variety of engineering leadership positions in both Operations and R&D at LifeScan, where he spent 12 years. Prior to LifeScan, Mr. Bennett held several engineering positions with Pechiney where he worked for seven years. Mr. Bennett holds a Bachelor of Science degree in Mechanical Engineering from the University of Wisconsin Madison.

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

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

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

Donald P. Wood has served as our Vice President of Operations since April 2003. From July 2001 to March 2003, Mr. Wood served as Vice President of Bone Health, a business unit of Quidel Corporation and was responsible for Bone Health Product Operations, Device Research and Development, and Sales and Marketing. He also served as

Quidel's Vice President of Ultrasound Operations from August 1999 to

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July 2001. Prior to joining Quidel, Mr. Wood was the Director of Ultrasound Operations for Metra Biosystems Inc. from July 1998 to August 1999. He also served as its Director of Operations from October 1995 to July 1998. Mr. Wood also served as Senior Director of Operations for BioChem Pharma Inc. from July 1994 to October 1995 and Mr. Wood held numerous positions within operations for Serono Diagnostics Inc. from 1980 to July 1994. Mr. Wood holds a Bachelor of Science degree in Business Administration from Bloomsburg University.

Available Information

Our website is located at <http://www.cholestech.com>. Electronic copies of our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available, free of charge, on the Investor section of our website as soon as practicable after we electronically file such material with the Securities and Exchange Commission. The contents of our website are not incorporated by reference in this Annual Report on Form 10-K.

The Company has adopted a code of ethics, which is part of our Code of Business Conduct and Ethics that applies to all of our directors, officers and associates of the Company. In addition, the Company has also adopted a Code of Ethics for Principal Executive and Senior Financial Officers. These Codes of Ethics are posted on the Company's website.

ITEM 1A: RISK FACTORS

The reader should carefully consider each of the risks and uncertainties we describe below, as well as all of the other information in this report. The risks and uncertainties we describe below are not the only ones we face. Additional risks and uncertainties which we are currently unaware of or that we currently believe to be immaterial could also adversely affect our business.

Risks related to the pending merger between Inverness and the Company.

In June 2007, we announced that we had signed a definitive merger agreement with Inverness pursuant to which Inverness would acquire the Company, in a stock-for-stock merger. The merger is expected to close in the fall of 2007, subject to the satisfaction of customary closing conditions, including the receipt of regulatory and Cholestech shareholder approvals to the merger. There can be no assurance that all of these conditions will be satisfied. If these conditions are not satisfied or waived, we may be unable to complete the merger.

Upon completion of the merger, Inverness will exchange 0.43642 shares of Inverness common stock for each outstanding share of the Company common stock, despite any changes in the market value of either common stock. Accordingly, the specific dollar value of Inverness common stock the Company's shareholders will receive upon completion of the merger will depend on the Inverness market value of the common stock at the time of completion of the merger. You should note that the Company and Inverness stock prices have historically been very volatile and that the value of the Inverness common stock the Company's shareholders will receive in the merger may decline prior to or after the merger.

As is typical with change of control transactions, Cholestech employees may experience uncertainty about their future role with the combined company. These employees may leave the Company prior to or after the closing of the merger. This may adversely affect the Company's ability to attract and retain key management, sales, marketing, technical and other personnel, pending the closing of the merger. Similarly, Cholestech's customers may, in response to the announcement of the merger, delay or defer purchasing decisions. Any delay or deferral in purchasing decisions by the Company's customers could harm the business of the Company in the short-term, and the combined company in the long-term.

If the merger is not completed, the price of the Company common stock may decline to the extent that the current market price of the Company reflects a market assumption that the merger will be completed. The management team would have been distracted from running the business and the Company will incur significant costs related to the merger, such as legal, accounting and some of the fees and expenses of their financial advisors, some of which costs must be paid even if the merger is not completed.

Although the Company and Inverness intend that the merger will result in benefits to the combined company, those benefits may not be realized. The integration of the companies will be a complex, time consuming and expensive process and may disrupt the companies' businesses, if not completed in an efficient manner. Failure to realize the expected benefits and/or disruption to the Company's business could materially harm the business and operating results of the combined company.

We have a history of fluctuating operating results, which may result in the market price of our common stock declining

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

- the timing and level of market acceptance of the LDX System and the GDX System;
- manufacturing problems, efficiencies, capacity constraints or delays;
- the timing of the introduction, availability and market acceptance of new tests and products;
- the timing of significant orders from, and shipments to, customers;
- variations in the mix of products sold;
- promotional program spending by both domestic and European pharmaceutical companies;
- changes in demand for our products based on changes in third-party reimbursement policies, changes in government regulation and other factors;
- product pricing and discounts;
- the timing and level of expenditures associated with research and development activities;
- the timing, establishment and maintenance of strategic distribution arrangements and the success of the activities conducted under such arrangements;
- competition from diagnostic companies with greater financial capital and resources;
- costs and timing associated with business development activities, including potential licensing of technologies or intellectual property rights;
- additions or departures of our key personnel;
- litigation or the threat of litigation; and
- adoption of new accounting standards, such as SFAS 123R.

These and other factors are difficult to predict and could have a material adverse effect on our business, financial condition and operating results. Fluctuations in quarterly demand for our products may cause our manufacturing operations to fluctuate in volume, increase uncertainty in operational planning and/or affect cash flows from operations. We commit to many of our expenses in advance, based on our expectations of

future business needs. These costs are largely fixed in the short-term. As a result, when

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business levels do not meet expectations, our fixed costs will not be recovered and we will experience losses. This situation is likely to result in the future because of the variability and unpredictability of our revenue. This also means that our results will likely not meet the expectations of public market security analysts or investors at one time or another, which may result in the market price of our common stock declining.

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

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

- our pending patent applications may not result in the issuance of any patents, or, if issued, such patents may not offer protection against competitors with similar technology;
- our patents may be challenged, invalidated or circumvented in the future, and the rights created under our patents may not provide a competitive advantage;
- competitors, many of whom have substantially greater resources than us and have made substantial investments in competing technologies, may seek to apply for and obtain patents covering technologies that are more effective than ours. This could render our technologies or products obsolete or uncompetitive or could prevent, limit or interfere with our ability to make, use or sell our products either in the United States or in international markets;
- the medical products industry has been characterized by extensive litigation regarding patents and other intellectual property rights; and
- an adverse determination in litigation or interference proceedings to which we may become a party could subject us to significant liabilities to third parties or require us to seek licenses from third parties, which may not be available on commercially reasonable terms or at all.

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

For example, in December 2003, we entered into a settlement agreement and license agreement with Roche, which settled all existing patent litigation between the parties on a worldwide basis. As a part of the settlement, we pay Roche an ongoing royalty and Roche granted an irrevocable, non-exclusive, worldwide license to us for its patents related to HDL cholesterol. In addition, the parties also agreed upon a mechanism for the resolution of future patent infringement disputes. Under the Roche license and settlement agreements, Cholestech is entitled to identify a design-around product that we believe does not require payment to Roche, and we have done so. Roche can request arbitration on this issue, and they have taken the first steps to initiate such proceedings. If no agreement is reached, an arbitration will be commenced to determine whether license payments must be made for the design-around. If, upon the resolution of any such dispute, it is ultimately determined that our new HDL cholesterol test cassette is

covered by Roche's patents, we will pay Roche the same ongoing royalty, as that agreed to under the Roche license and settlement agreements.

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

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

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

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

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

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

- third-party payors are increasingly scrutinizing and challenging the prices charged for both existing and new medical products and services;
- healthcare providers are moving toward a system in which employers are requiring participants to bear a greater burden of the cost of their healthcare benefits which could result in fewer elective procedures, such as the use of our products for diagnostic screening;
- general uncertainty regarding what changes will be made in the reimbursement methods used by third-party payors and how that will affect the use of products such as ours, which may deter healthcare providers from adopting the use of our products; and
- an overall escalating cost of medical products and services has led to and will continue to lead to increased pressures on the healthcare industry, both domestic and international, to reduce the cost of products and services, including products offered by us.

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

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

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

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

To increase revenue and achieve sustained profitability, we will have to successfully maintain our existing distribution relationships and develop new distribution relationships. We depend on our distributors to assist us in promoting market acceptance of the LDX System and the GDx System. However, we may be unable to enter into and maintain new arrangements on a timely basis, or at all. Even if we do enter into additional distributor relationships, those distributors may not devote the resources necessary to provide effective sales and marketing support to our products. In addition, our distributors sell products offered by our competitors. If our competitors offer our distributors more favorable terms or have more products available to meet their needs or utilize the leverage of broader product lines sold through the distributor, those distributors may de-emphasize or decline to carry our products. In addition, our distributors' order decision-making process is complex and involves several factors, including end-user demand, warehouse allocation and marketing resources, which can make it difficult to accurately predict total sales for the quarter until late in the quarter. In order to keep our products included in distributors' marketing programs, in the past we have provided promotional goods or made short-term pricing concessions. The discontinuation of promotional goods or pricing concessions could have a negative effect on our business. Our distributors could also modify their business practices, such as payment terms, inventory levels or order patterns. If we are unable to maintain successful relationships with distributors or expand our distribution channels or we experience unexpected changes in payment terms, inventory levels or other practices by our distributors, our business will suffer.

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

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

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

The market for diagnostic products in which we operate is intensely competitive. Our business is based on the sale of diagnostic products that physicians and other healthcare providers can administer in their own facilities without sending samples to laboratories. Thus, our competition consists primarily of clinical reference laboratories and hospital-based laboratories that use automated testing systems, as well as manufacturers of other rapid diagnostic tests. To achieve and maintain market acceptance for the LDX System, we must demonstrate that the LDX System is a cost effective and time saving alternative to other rapid diagnostic tests, as well as to clinical and hospital laboratories. Even if we can demonstrate that our products are more cost effective and save time, physicians and other healthcare providers may resist changing their established source of such tests. The LDX System may be unable to compete with these other testing services and analyzers. In addition, companies with a significant presence in the market for clinical diagnostics, such as Abbott Laboratories, Bayer Diagnostics, Beckman Coulter, Inc. and Roche Diagnostics (a subsidiary of Roche Holdings, Ltd.) have developed or are developing analyzers designed for point of care testing. These competitors have substantially greater financial, technical, research and other resources and larger, more established marketing, sales, distribution and service organizations than us. These competitors also offer broader product lines than us, have greater name recognition than us and offer discounts as a competitive tactic. In addition, several smaller companies are currently making or developing products that compete or will compete with ours. We may not have the financial resources, technical expertise or marketing, distribution or support capabilities to compete successfully in the future. Even if we do have such resources and capabilities, we may not employ them successfully.

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

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

- a decrease in the amount of reimbursement for performing tests on the LDX System.
- many managed care organizations have contracts with laboratories, which require participating or employed physicians to send patient specimens to contracted laboratories; and
- physicians are under growing pressure by Medicare and other third-party payors to limit their testing to medically necessary tests.

If our LDX System does not achieve broader market acceptance, our business will not grow. Even if we are successful in continuing to place our LDX Analyzer at physician office laboratories and other near-patient testing sites, there can be no assurance that placement of these products will result in sustained demand for our single use test cassettes.

In addition, we must leverage our installed base of systems in order to increase the sales of our single use test cassettes and single use test cartridges. If we are unable to increase the usage of cassettes on our current installed base, we will have to identify new customers and induce them to purchase an analyzer, which requires more time and effort and has a significantly larger purchase price than the single use test cassettes.

As a result of these many hurdles to achieving broad market acceptance for the LDX System, demand 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.

If we do not successfully develop, acquire or form alliances to introduce and market new tests and products, our future business will be harmed

We believe our business will not grow significantly if we do not develop, acquire or form alliances for new tests and products to use in conjunction with the LDX System and the GDX System. If we do not develop market and introduce new tests and products to the market, our business will not grow significantly and will be harmed. Developing new tests involves many significant problems and risks, including:

- research and development is a very expensive process;
- research and development takes a very long time to result in a marketable product;
- significant costs (including diversion of resources) may be incurred in development before knowing if the development will result in a test that is commercially viable;
- a new test will not be successful unless it is effectively marketed to its target market;
- the manufacturing process for a new test must be reliable, cost efficient and high volume and must be developed and implemented in a timely manner to produce the test for sale;
- new tests must meet a significant market need to be successful; and
- new tests must obtain proper regulatory approvals to be marketed.

We could experience difficulties that delay or prevent the successful development, introduction and marketing of new tests and products. For example, regulatory clearance or approval of any new tests or products may not be granted on a timely basis, or at all. We have experienced difficulties obtaining regulatory approval for tests in the past. Because the evaluation of applications by the FDA for CLIA waived status is not based on precisely defined, objectively measurable criteria, we cannot predict the likelihood of obtaining CLIA waived status for future products. In addition, our business strategy includes entering into agreements with clinical and commercial collaborators and other third parties for the

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

We face risks from failures in our manufacturing processes

We manufacture all of the single use test cassettes that are used with the LDX Analyzer. The manufacture of single use test cassettes is a highly complex and precise process that is sensitive to a wide variety of factors. Significant additional resources, implementation of additional manufacturing equipment or changes in our manufacturing processes have been, and may continue to be, required for the scaling-up of each new product prior to commercialization or in order to meet increasing customer demand once commercialization begins, and this work may not be completed successfully or efficiently. In the past, we have experienced lower than expected manufacturing yields that have adversely affected gross margins and delayed product shipments. If we do not maintain acceptable manufacturing yields of test cassettes or experience product shipment delays, our business, financial condition and operating results could be materially adversely affected. We may reject or be unable to sell a substantial percentage of test cassettes because of:

- raw materials variations or impurities;
- human error;
- manufacturing process variances and impurities; and
- decreased manufacturing equipment performance.

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

- as our production levels increase, we could be required to use our machinery more hours per day and the down time resulting from equipment failure could increase;
- 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 of our cassettes at our Hayward, California manufacturing facility, so manufacturing operations are at risk to interruption from earthquake, fire, power outages or other events affecting this one location.

Our future results could be harmed by economic, political, regulatory and other risks associated with international sales

Historically, a significant portion of our total revenue has been generated outside of the United States. International revenue as a percentage of our total revenue was approximately 13% in fiscal year 2007 and 2006, and approximately 14% in fiscal year 2005. We anticipate that international revenue will continue to represent a significant portion of our total revenue in the future. Our revenue is generally denominated in United States dollars; however, a strengthening of the dollar could make our products less competitive in foreign markets and, as a result, our future revenue from international operations may be unpredictable. We make foreign currency denominated purchases related to our GDX System in the United Kingdom. This exposes us to risks associated with currency exchange fluctuations.

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

- our dependency on pharmaceutical companies' promotional programs as a primary source of international revenue;
- unexpected changes in regulatory requirements;
- the impact of recessions in economies outside the United States;
- changes in a specific country's or region's political or economic conditions, particularly in emerging nations;
- less effective protection of intellectual property rights in some countries;
- changes in tariffs and other trade protection measures;
- difficulties in managing international operations; and
- potential insolvency of international distributors and difficulty in collecting accounts receivable and longer collection periods.

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

We depend on single source suppliers for certain materials used in our manufacturing process and failure of our suppliers to provide materials to us could harm our business

We currently depend on single source vendors to provide certain subassemblies, components and raw materials used in the manufacture of our products. We also depend on a third-party manufacturer for the GDX System. Any supply interruption in a single sourced material or product could restrict our ability to manufacture and distribute products until a new source of supply is identified and qualified. We may not be successful in qualifying additional sources of supply on a timely basis, or at all. Failure to obtain a usable alternative source or product could prevent us from manufacturing and distributing our products, resulting in inability to fill orders, customer dissatisfaction and loss of business. This would likely severely harm our business. In addition, an uncorrected impurity or supplier's variation in material, either unknown to us or incompatible with our manufacturing process, could interfere with our ability to manufacture and distribute products. Because we are a small customer of many of our suppliers and we purchase their subassemblies, components and materials with purchase orders instead of long-term commitments, our suppliers may not devote adequate resources to supplying our needs. Any interruption or reduction in the future supply of any materials currently obtained from single or limited sources could severely harm our business.

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

Sales to a limited number of customers have accounted for a significant portion of our revenue in each fiscal period. We expect that sales to a limited number of customers will continue to account for a substantial portion of our total revenue in future periods. Our top ten customers comprised approximately 65% of our revenue in fiscal year 2007. In fiscal year 2007, Physicians Sales and Service accounted for approximately 21% of our total revenue, Henry Schein Inc. accounted for approximately 10% and McKesson Medical Surgical accounted for approximately 8% of our total revenue. In fiscal year 2006, Physicians Sales and Service accounted for approximately 22% of our total revenue, Henry Schein Inc. accounted for approximately 11% and McKesson Medical Surgical accounted for approximately 7% of our total revenue. In fiscal year 2005, Physicians Sales and Service accounted for approximately 24% of our total revenue, Henry Schein Inc. accounted for approximately 9% and McKesson Medical Surgical accounted for approximately 7% of our total revenue. We have experienced periods in which sales to some of our major customers, as a percentage of total revenue, have fluctuated due to delays or failures to place expected orders. We do not have long-term agreements with any of our customers, who generally purchase our products pursuant to cancelable short-term purchase orders. If we were to lose a major customer or if orders by or shipments to a major customer were to otherwise decrease or be delayed, our operating results would be harmed.

While we believe that we currently have adequate internal control over financial reporting, we are exposed to risks from recent legislation requiring companies to evaluate internal control over financial reporting

Section 404 of the Sarbanes-Oxley Act of 2002 requires our management to report on and our independent registered public accounting firm to attest to the effectiveness of our internal control over financial reporting. We have an ongoing program to perform the system and process evaluation and testing necessary to comply with these requirements.

We expect to continue to incur significant expenses and to devote significant resources to Section 404 compliance on an ongoing basis. In addition, it is difficult for us to predict how long it will take to complete the assessment of the effectiveness of our internal control over financial reporting each year and we may not be able to complete the process on a timely basis. In the event that internal controls over financial reporting are not effective as defined under Section 404, we cannot predict how regulators will react or how the market prices of our shares will be affected. In addition, if we fail to maintain an effective system of internal control or if we were to discover material weaknesses in our internal control systems, we may be unable to produce reliable financial reports or prevent fraud and it could harm our results of operations and financial condition.

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

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

regulatory requirements, we may be unable to market the affected products, which would depress our revenue and severely harm our business.

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

- the 510(k) pre-market notification process, which generally takes from two to four months but may take longer; and
- the pre-market approval process (PMA), 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 six months to a year but may take significantly longer.

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

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

The LDX Analyzer, our total cholesterol, high density lipoproteins, triglycerides and glucose tests in any combination, our ALT test cassette, the GDX Analyzer and A1C test cartridges have been classified as waived from the application of many of the requirements under the CLIA. We believe this waived classification is critical for our products to be successful in their domestic markets. Any failure of our new tests to obtain waived status under the CLIA will severely limit our ability to commercialize such tests. Loss of waived status for existing diagnostic products or failure to obtain waived status for new products could limit our revenue from sales of such products, which would severely harm our business.

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

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

- ISO 13485:2003 requirements, which is an industry standard for maintaining and assuring conformance to quality management systems; and
- Canadian Medical Devices Conformity Assessment System (CMDCAS), which implements Canadian regulations requiring medical devices be designed and manufactured under a registered quality management system.
- 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 could be negatively affected by the loss of key personnel or our inability to hire qualified personnel

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

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

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

We currently maintain product liability insurance and professional liability insurance for claims relating to the past performance of testing services, but there can be no assurance that the coverage limits of our insurance policies will be adequate. Insurance is expensive and difficult to obtain, and we may be unable to maintain product liability insurance in the future on acceptable terms or in sufficient amounts to protect us against losses due to product liability. Inability to maintain insurance at an acceptable cost or to otherwise protect against potential product liability could prevent or inhibit the continued commercialization of our products. In addition, a product liability or professional liability claim in excess of relevant insurance coverage or a product recall could severely harm our financial condition.

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

The market price of our common stock has in the past been, and in the future is likely to be, highly volatile. For example, between April 1, 2006 and March 30, 2007, the price of our common stock, as reported on the NASDAQ Stock Market LLC, has ranged from a low of \$10.67 to a high of \$19.35. These fluctuations could result in substantial losses for investors. Our stock price may fluctuate for a number of reasons including:

- quarterly variations in our operating results;
- litigation or threat of litigation;
- developments in or disputes regarding patent or other proprietary rights;
- announcements of technological or competitive developments by us and our competitors;
- regulatory developments regarding us or our competitors;
- changes in the current structure of the healthcare financing and payment systems;

- our failure to achieve, or changes in, financial estimates by securities analysts and comments or opinions about us by securities analysts or major shareholders;
- stock market price and volume fluctuations, which have particularly affected the market prices for medical products and high technology companies and which are often unrelated to the operating performance of such companies; and
- general economic, political and market conditions.

With the advent of the internet, new avenues have been created for the dissemination of information. We do not have control over the information that is distributed and discussed on electronic bulletin boards and investment chat rooms. The motives of the people or organizations that distribute such information may not be in our best interest or in the interest of our shareholders. This, in addition to other forms of investment information, including newsletters and research publications, could result in a significant decline in the market price of our common stock.

In addition, stock markets have from time to time experienced extreme price and volume fluctuations. The market prices for diagnostic product companies have been affected by these market fluctuations and such effects have often been unrelated to the operating performance of such companies. These broad market fluctuations may cause a decline in the market price of our common stock.

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

ITEM 1B: *UNRESOLVED STAFF COMMENTS*

None

ITEM 2: *PROPERTIES*

Our offices are located in an approximately 69,000 square foot leased facility in Hayward, California. Our facilities contain approximately 17,000 square feet of warehouse space, 7,000 square feet of manufacturing space, 5,000 square feet of laboratory space and the balance devoted to marketing and administrative and common areas. Our lease pertaining to this facility expires in April 1, 2017. We expect that our current leased facilities will be sufficient for our needs over the next 12 months.

ITEM 3: *LEGAL PROCEEDINGS*

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

On March 14, 2003, the Company initiated trademark infringement proceedings against Euromedix before the President of the Commercial Court in Leuven, Belgium (No. BRK/03/00017), seeking in principle an order (i) to prohibit Euromedix from selling, stocking, importing, exporting or promoting in the European Economic Area (EEA) products that violate the Company's trademarks, under a penalty

of 10,000 Euros for each LDX-Analyzer sold, a penalty of 1,000 Euros for each cassette sold contrary to the prohibition and a 25,000 Euros penalty for each publicity of advertisement; (ii) to prohibit Euromedix from using certain slogans and phrases, in combination with products associated with certain of the Company's trademarks, in trade documents or other announcements, under a penalty of 25,000 Euros for each document used contrary to this prohibition; and (iii) to order the destruction of the inventory of products held by Euromedix that violate the Company's trademarks, which have been imported into the EEA without the Company's permission.

A hearing was held on April 29, 2003 regarding certain procedural issues. In a judgment rendered on May 27, 2003, the Judge of Seizures of the Court of First Instance referred the complaint to the Constitutional Court before rendering a final decision. The Judge of Seizures asked the Constitutional Court to render an opinion regarding certain constitutional issues related to the trademark infringement arguments the Company raised at the hearing. Hearings in the Constitutional Court were held on July 8, 2003 and September 9, 2003. On March 24, 2004, the Constitutional Court issued its judgment which supported the Company's claims. A hearing was scheduled for November 9, 2004 by the Judge of Seizures of the Court of First Instance to hear additional submissions. On December 21, 2004, the Judge of Seizures of the Court of First Instance decided against Euromedix's opposition to certain procedural issues.

After the decisions of the Judge of Seizures of the Court of First Instance, the Company filed requests for a procedural calendar in the three trademark infringement proceedings against Euromedix of which two are pending before the President of the Commercial Court of Leuven and one before the Commercial Court of Leuven. Both parties have exchanged submissions. All three cases were pleaded at a hearing on June 21, 2005 and were taken into deliberation. On September 13, 2005, a judgment was rendered in favor of the Company regarding items (i) and (ii) above. A judgment has not yet been rendered on item (iii).

Euromedix filed a request for a procedural calendar in the case pending before the Commercial Court of Leuven regarding the termination of the business relationship on July 11, 2002. On December 13, 2005, the Commercial Court of Leuven decided in an interim decision that the termination of the relationship is not governed by Belgian law, but Californian law and allowed the parties to file further submissions in order to substantiate the claims under Californian law. Euromedix has appealed the ruling of the Commercial Court of Leuven and the appeal will be initiated at a hearing on September 21, 2007 before the First Chamber of the Court of Appeal of Brussels.

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

None.

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

Our common stock is quoted on the NASDAQ Stock Market LLC under the symbol CTEC. On March 30, 2007, the last reported sale price for our common stock on the NASDAQ Stock Market LLC was \$17.24 per share. The following table sets forth the quarterly high and low trading prices for our common stock as reported by the NASDAQ Stock Market LLC for the periods indicated.

	High	Low
FISCAL YEAR 2006		
First Quarter	\$ 11.71	\$ 7.95
Second Quarter	11.89	9.47
Third Quarter	11.00	7.99
Fourth Quarter	13.19	9.29
FISCAL YEAR 2007		
First Quarter	\$ 14.11	\$ 12.09
Second Quarter	13.02	10.67
Third Quarter	19.00	12.16
Fourth Quarter	19.35	15.97

As of March 30, 2007, there were 15,564,749 shares of our common stock issued and outstanding and held by approximately 124 holders of record. We estimate that there are approximately 5,500 beneficial owners of our common stock.

Dividend Policy

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

Equity Compensation Plans

The information required by this item regarding equity compensation plans is incorporated by reference under the section entitled *Equity Compensation Plan Information* contained in our proxy statement for our 2007 annual meeting of shareholders.

Stock Performance Graph

Notwithstanding any statement to the contrary in any of our previous filings with the SEC, the following information relating to the price performance of our Common Stock shall not be deemed filed with the SEC or Soliciting Material under the Securities Exchange Act of 1934, as amended, or subject to Regulation 14A or 14C, or to liabilities of Section 18 of the Exchange Act except to the extent we specifically request that such information be treated as soliciting material or to the extent we specifically incorporate this information by reference.

The graph below matches Cholestech Corporation's cumulative 5-year total shareholder return on common stock with the cumulative total returns of the NASDAQ Composite index and the NASDAQ Medical Equipment index. The graph tracks the performance of a \$100 investment in our common stock and in each of the indexes (with the reinvestment of all dividends) from 3/31/2002 to 3/31/2007.

	3/02	3/03	3/04	3/05	3/06	3/07
Cholestech Corporation	100.00	45.55	49.25	56.41	72.92	96.48
NASDAQ Composite	100.00	71.63	109.32	109.98	131.49	138.22
NASDAQ Medical Equipment	100.00	91.68	140.11	147.32	180.00	188.44

The stock price performance included in this graph is not necessarily indicative of future stock price performance

ITEM 6: SELECTED FINANCIAL DATA

The following selected financial data should be read in conjunction with our financial statements and notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations. The following selected statement of operations data for the fiscal years ended March 30, 2007, March 31, 2006, and March 25, 2005 and the selected balance sheet data as of March 30, 2007 and March 31, 2006 are derived from, and qualified by reference to, the audited financial statements included elsewhere in this Annual Report on Form 10-K. The selected statement of operations data for the fiscal year ended March 26, 2004 and March 28, 2003 and the balance sheet data as of March 25, 2005, March 26, 2004 and March 28, 2003 have been derived from our audited financial statements not included in this Annual Report. These historical results are not necessarily indicative of the results of operations to be expected from any future period.

	Year Ended March 31,(1)				
	2007	2006	2005	2004	2003
	(In thousands, except per share data)				
Statement of Operations Data:					
Revenue	\$ 69,526	\$ 64,093	\$ 52,877	\$ 52,376	\$ 48,541
Cost of revenue	23,042	23,902	21,390	23,180	20,424
Gross profit	46,484	40,191	31,487	29,196	28,117
Operating expenses:					
Sales and marketing	14,785	13,036	11,494	12,654	11,737
Research and development	6,280	7,553	4,252	3,159	2,722
General and administrative	13,718	11,230	9,864	8,153	7,008
Other operating costs				250	
Litigation and other related				7,786	307
Total operating expenses	34,783	31,819	25,610	32,002	21,774
Income (loss) from operations	11,701	8,372	5,877	(2,806)	6,343
Interest and other income, net	2,158	923	243	334	438
Income (loss) before taxes	13,859	9,295	6,120	(2,472)	6,781
Provision (benefit) for income taxes(2)	4,453	3,661	1,972	(11,179)	(3,934)
Income from continuing operations	9,406	5,634	4,148	8,707	10,715
Loss from discontinued operations					(1,377)
Loss from sale of discontinued operations					